

## Decree of 16 July 16 laying down the Radiation Protection Decree

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We Beatrix, by the grace of God Queen of the Netherlands, Princess of Orange-Nassau, etc., etc., etc.

On the recommendation of 20 December 2000 of the State Secretary for Social Affairs and Employment, J. F. Hoogervorst, Health and Safety at Work Directorate, No. Arbo/Amil/00/84346, made also on behalf of Our Minister of Housing, Spatial Planning and the Environment and Our Minister of Health, Welfare and Sport, in agreement with Our Minister of Economic Affairs;

Having regard to Sections 28, 29 (1), 30, 31, 32 (1) and (4), 34, 35, 37 (1), 37a, 38a, 67, 69 (4) and (5), 69a, 69b, 73 and 76 of the Nuclear Energy Act, Section 16 of the Health and Safety at Work Act, Section 37 (2) of the Individual Health Care Occupations Act and European Union Council Directive No. 96/29/Euratom of 13 May 1996 laying down basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation (OJEU L 159) and European Council Directive No. 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom (OJEU L 180);

Having heard the Council of State (recommendation of 27 March 2001, No. W12.01.0024/IV);

Having regard to the further report of 2 July 2001 of the State Secretary for Social Affairs and Employment, J. F. Hoogervorst, Health and Safety at Work Directorate, No. Arbo/Amil/01/41134, also made on behalf of Our Minister of Housing, Spatial Planning and the Environment and Our Minister of Health, Welfare and Sport, in agreement with Our Minister of Economic Affairs;

Have approved and decreed:

### Part 1: Definitions and Scope

#### Article 1

1. In this Decree and the provisions based upon it the following terms are defined as follows:

*indicator*: instrument for determining time or place or for measuring, determining or indicating other parameters, designed for use on or in the immediate environs of persons;

*activity*: activity as referred to in the Annex;

*activity concentration*: activity concentration as referred to in the Annex;

*disused high-activity source*: high-activity source that is no longer being used and is not designed to be used for the practice for which a licence has been granted;

*general coordinating expert*: radiation protection expert who ensures on behalf of the undertaking that practices or work activities take place within the framework of the rules in or pursuant to the Act, who supervises this and carries out checks, who coordinates other matters relating to radiation protection and on behalf of the undertaking grants permission internally for practices and work activities;

*health and safety service*: a service as referred to in the Health and Safety at Work Act;

*category A worker*: an exposed worker as referred to in Article 79 (2);

*management of radioactive wastes*: all activities related to the handling, pretreatment, treatment, conditioning, storage or disposal of radioactive wastes, with the exception of transport outside the site of the facility;

*management system*: system containing data and documents relating to radiation protection in the undertaking;

*contamination*: the presence of radioactive substances in a material, in or on a surface, in an environment, or externally or internally in a person;

*security expert*: expert on the storage and security of fuels, ores, facilities as referred to in Section 15 (a) and (b) of the Act, and radioactive substances, as referred to in cases to be designated by Ministerial Regulation;

*exposed worker*: worker who during his working hours undergoes exposure as a result of practices that could result in a dose higher than one of the dose limits laid down in Article 76;

*exposure*: being exposed to ionizing radiation;

*source*: apparatus or a radioactive substance;

*source container*: source containment system that is not an integral part of the source but intended solely as temporary casing for that source for transport, transshipment, etc.;

*source holder*: housing of a sealed source which at the exit window of the source holder is fitted with a device enabling the exiting beam to be interrupted and from which the source cannot be removed without tools;

*category B worker*: exposed worker other than a category A worker;

*Annex*: the Annex to this Decree;

*coordinating expert*: radiation protection expert who ensures on behalf of the undertaking that practices or work activities take place within the framework of the rules in or pursuant to the Act, who supervises this and carries out checks and coordinates other matters relating to radiation protection;

*expert*: a person holding a diploma, certificate or other document attesting completion of training in the field of radiation protection obtained from an institution as referred to in Article 7f;

*dose constraint*: dose laid down, when planning practices, as the ceiling value for the process of optimizing protection against ionizing radiation in a practice, duty or occupation or category thereof;

*effective dose*: effective dose as referred to in the Annex;

*committed effective dose*: committed effective dose as referred to in the Annex;

*disposal*: placement of radioactive wastes or spent fuels in a facility with no intention of retrieving those wastes or fuels;

*equivalent dose*: equivalent dose as referred to in the Annex;

*outside worker*: category A worker working on Dutch territory in an area as referred to in Article 83 (1) (a) (i) under the responsibility of an undertaking registered in another European Union Member State member state or a third country;

*health detriment*: the estimated likelihood of shorter lifespan and impaired quality of life for a person owing to the negative effects of physical abnormalities, cancer and serious genetic effects caused by exposure to ionizing radiation;

*practice*: the preparation, holding, use or discarding of an artificial source or a natural source, insofar as this natural source has been or is being processed with a view to its radioactive properties, or the use or holding of apparatus, except in the case of an intervention, accident or radiological emergency;

*high-activity source*: sealed source containing a radionuclide whose activity exceeds a value equal to or higher than the activity level laid down for that source pursuant to Article 3 (1);

*industrial radiography*: by means of ionizing radiation from apparatus or a device, generating a visual image by converting the signal generated into a video signal that is reproduced on a monitor or a method whereby the projection of the object under examination is recorded on film material;

*sealed source*: radioactive substances embedded in or attached to solid carrier material or surrounded by a casing of material, subject to the proviso that either the carrier material or the casing is sufficiently strong to prevent any dispersal of radioactive substances under normal conditions of use;

*inspector*: official designated as such by decree of Our Minister of Economic Affairs, Agriculture and Innovation;

*artificial source*: source other than a natural source and other than apparatus;

*supplier*: natural or legal person supplying or providing a high-activity source;

*member of the public*: a member of the public inside or outside a location other than a worker during his working hours or a person undergoing a radiological procedure;

*location*: facility as designated pursuant to Section 1.1 (3) of the Environmental Management Act, or place where a practice or work activity is carried out;

*discharge*: discharge onto or into the ground, into the air, into a public sewer or into surface water;

*discharge onto or into the ground*: finally placing onto or into the ground of liquid radioactive substances or radioactive substances dissolved in liquid or particles of radioactive substances carried in a flow of liquid, or causing them to be thus placed, or placing these substances on the ground if in the process some liquid enters the ground, other than fertilizers as referred to in Section 1 (1) of the Fertilizers Act;

*discharge into a public sewer*: escape into a public sewer of liquid radioactive substances or radioactive substances dissolved in liquid or particles of radioactive substances carried in a flow of liquid, or causing them to thus escape;

*discharge into the air*: escape into the air of gaseous radioactive substances or particles of radioactive substances carried in a flow of gas, or causing them to thus escape;

*discharge into surface water*: escape into surface water of liquid radioactive substances or radioactive substances dissolved in liquid or particles of radioactive substances carried in a flow of liquid, or causing them to thus escape;

*monitoring, control or calibration source*: source used solely in a monitoring, control or calibration setup, fixed or otherwise;

*radiation incident hotline*: hotline referred to in Article 12a;

*mining*: practices or work activities connected with carrying out exploration, detecting or extracting minerals or geothermal heat, or storing substances;

*natural source*: cosmic radiation or source of natural origin other than apparatus;

*environmental dose equivalent*: environmental dose equivalent as referred to in the Annex;

*environmental dose equivalent rate*: environmental dose equivalent rate as referred to in the Annex;

*undertaking*: the person under whose responsibility a practice or work activity is carried out;

*unintended dispersal*: unintended dispersal of a radioactive substance as a result of a practice or work activity carried out under the responsibility of an undertaking and which is no longer under the control of the undertaking concerned;

*Our Minister*: Our Minister of Economic Affairs;

*Our Ministers*: Our Ministers of Economic Affairs and Social Affairs & Employment;

*open source*: source other than a sealed source and other than apparatus;

*surface contamination*: surface contamination as referred to in the Annex;

*excessive irradiation*: exposure whereby the effective dose or equivalent dose referred to in Articles 76, 77 and 78 is exceeded;

*excessive exposure*: exposure taking place in an unforeseeable or unintended event that could result in exposure higher than laid down in the risk analysis;

*potential exposure*: exposure that is not certain to occur but the likelihood of which and the magnitude of any exposure that occurs can be anticipated and which has been determined before the start of the practices and work activities with the aid of a risk analysis;

*radioactive waste*: radioactive substance designated as such pursuant to Article 38 and which is not discharged;

*radiological procedure*: medical procedure using ionizing radiation as referred to in Article 53 (1);

*radiotoxicity equivalent*: activity that on intake produces a committed effective dose of 1 sievert in an adult reference person;

*normal exposure*: exposure under normal operating conditions which has been estimated before the start of the practices or work activities with the aid of a risk analysis;

*Directive 2011/77/Euratom*: Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste (OJEU 2011, L 199);

*risk analysis*: risk survey and evaluation as referred to in Section 5 (1) of the Health and Safety at Work Act;

*damage*: harmful effects of ionizing radiation on humans, animals, plants and property;

*radiation physician*: a person registered as a radiation physician in the register referred to in Article 7 (1);

*radiation incident*: unforeseen event, situation or unintended dispersal where there is danger, or danger has occurred, other than normal or potential exposure, of:

- exposure to ionizing radiation of members of the public exceeding 0.1 mSv per year,
- discharge onto or into the ground, into a sewer, into surface water or into the air exceeding a value laid down by Our Minister, or
- excessive exposure or excessive irradiation of workers;

*supervisory expert*: expert carrying out a practice or work activity, or under whose supervision a practice or work activity is carried out;

*worker*: person carrying out work, either in the service of or under the authority of an undertaking or

as a self-employed person;

*work activity*: the preparation, holding, use or discarding of a natural source, insofar as it is not being/has not been processed on account of its radioactive properties, except in the case of an intervention, accident or radiological emergency;

*Act*: the Nuclear Energy Act.

2. In this Decree and the provisions based upon it 'holding' includes generating, processing, handling and storing, with the exception of storage in connection with transport.
3. For the purposes of this Decree and the provisions based upon it, economic and social factors shall be taken into account when deciding what is 'reasonably possible'. In addition, in the case of exposure the extent to which exposure and the likelihood of exposure can be limited shall be taken into account.

## Article 2

This Decree does not apply to:

- a. discharge or discarding of radioactive substances to which the prohibitions in Articles 35, 37 and 108 do not apply;
- b. transport of radioactive substances outside a location and bringing them, or causing them to be brought, onto or out of Dutch territory;
- c. transport of apparatus that is not used during transport;
- d. practices involving apparatus with a maximum high tension of 5 kV;
- e. exposure to radon and its progeny from the undisturbed earth's crust or from building materials used in buildings;
- f. above-ground exposure to radionuclides in the undisturbed earth's crust or in building materials used in buildings;
- g. ionizing radiation from radionuclides that are naturally present in the human body;
- h. cosmic radiation at the earth's surface;
- (i) cosmic radiation in an aircraft on members of the public and workers not part of the aircraft crew;
- j. exposure to radon and its progeny released when burning or blowing off natural gas.

## Article 3

1. Rules shall be laid down by regulation of Our Minister:
  - a. on the determination of environmental dose equivalents;
  - b. on the determination of equivalent and effective doses;
  - c. on the values for activity concentrations and total radionuclide activity;
  - d. on the designation of radionuclides exempted from aggregation when assessing natural sources;
  - e. on the determination of radionuclide activity levels.
2. The following may be done by regulation of Our Minister:
  - a. methods designated for the way in which the doses referred to at 1 (b) are checked against the doses laid down in this Decree;
  - b. rules laid down on methods for measuring activities, activity concentrations or surface contamination.
3. In order to determine doses, all the effective or equivalent doses that a person receives as a result of practices and work activities, insofar as regulated in or pursuant to this Decree, shall be aggregated, with the exception of a radiological procedure, in or pursuant to the Nuclear Facilities, Fissionable Materials and Ores Decree and in or pursuant to the Fissionable Materials, Ores and Radioactive Materials (Transport) Decree.

4. In order to assess the values determined pursuant to 1 (c), all the activities present or being discharged at a location at any time shall be weighted and aggregated insofar as laid down in or pursuant to this Decree, in or pursuant to the Nuclear Facilities, Fissionable Materials and Ores Decree and in or pursuant to the Fissionable Materials, Ores and Radioactive Materials (Transport) Decree.
5. Notwithstanding (4), activities or activity concentrations in natural sources shall not be aggregated with activities or activity concentrations in artificial sources.

## **Part 2: Justification and Optimization**

### **Article 4**

1. A practice is only permitted if it has been justified by Our Minister or is in a category of practices justified by Our Minister. Our Minister shall justify a practice or category of practices only if the economic, social and other benefits of the practice or category of practices concerned outweigh the health detriment that it could cause.
2. Rules shall be laid down by regulation of Our Minister on the declaration of:
  - a. what practices or categories thereof are justified in accordance with (1), and
  - b. what practices or categories thereof are not justified in accordance with (1).
3. If important new data on the effectiveness or consequences of the practices included therein so warrants, the justification of the practice may be revised. Any change as referred to in the previous sentence shall enter into force as soon as is reasonably possible.
4. If a licence is applied for or notification given of a practice that has been declared as justified, the notification or licence application shall refer to that declaration.
5. If a licence is applied for or notification given of a practice that has not been declared, or has been declared as not justified, the licence application or notification respectively shall include a request for justification of that practice. In that case the licence application or notification shall include such data on the economic, social and other benefits of the practice concerned and on the health detriment that it could cause as are needed to assess whether the practice is justified.
6. This Article does not apply to justification as referred to in Articles 55, 56 and 57.
7. In addition to the practices or categories of practices justified pursuant to (1), Our Minister of Defence, with a view to the interests served by the armed forces, may justify another practice or category of practices. This practice or category of practices shall be declared by Our Minister of Defence in a manner to be laid down by regulation of that Minister.
8. Applying Section 28 (1, last part of sentence) of the Services Act, Section 4.1.3.3 of the General Administrative Law Act shall not apply to a request for justification as referred to at (1) and (7).

### **Article 5**

1. The undertaking shall ensure that the effective or equivalent doses received by individual persons, in conjunction with the number of persons exposed, as a result of a practice are as low as is reasonably possible.
2. The undertaking shall ensure as regards potential exposures that both the dose in the event of exposure and the risk of exposure are as low as is reasonably possible.

### **Article 6**

1. Without prejudice to Article 48, the undertaking shall ensure that places at a location where practices are carried out are set up in such a way that as a result of all the practices together a dose constraint of 1 mSv effective dose in one calendar year is maintained for persons outside the

location.

2. The undertaking shall ensure that when carrying out practices notified in accordance with Article 21, as a result of all those practices together a dose constraint of 10  $\mu$ Sv effective dose in one calendar year is maintained for persons at any point outside the location.
3. If it is not reasonably possible to meet the obligation referred to at (1) by means of structural measures, it shall be met by means of organizational measures.
4. Other dose constraints may be laid down by regulation of Our Minister or Our Minister of Social Affairs and Employment for categories of practices, duties or positions designated therein.

### **Part 3: General Requirements**

#### **§3.1. Powers and duties of the radiation physician and the general coordinating expert, coordinating expert and supervisory expert**

##### **Article 7**

1. The duties to be performed under this Decree by a radiation physician shall only be carried out by a person registered by Our Minister as a radiation physician in a register maintained by Our Minister who carries out his duties in agreement with a person as referred to in Section 14 (1) of the Health and Safety at Work Act entrusted with the duties referred to in Section 14 (1) (b) or (c) of that Act or the health and safety service.
2. Requirements concerning the knowledge, skills and capabilities needed for registration as a radiation physician in the register referred to at (1) shall be laid down by regulation of Our Minister of Social Affairs and Employment.
3. Registration in a register as referred to at (1) may be refused or struck off if the requirements laid down in or pursuant to the Act or this Decree are not met or not fully met.
4. Rules shall be laid down by regulation of Our Minister of Social Affairs and Employment on:
  - a. the method of registration;
  - b. the data and documents to be furnished with an application for registration;
  - c. the grounds on which and cases in which registration may be refused or struck off.
5. Applying Section 28 (1, last part of sentence) of the Services Act, Section 4.1.3.3 of the General Administrative Law Act shall not apply to an application for registration as referred to at (1).

##### **Article 7a**

On application Our Minister shall register in the register referred to in Article 7 (1) a person who is a subject of a state concerned as referred to in Section 1 of the Recognition of EC Professional Qualifications Act if it has been demonstrated under Section 6 of the Recognition of EC Professional Qualifications Act that this person holds qualifications equivalent to the qualifications required by the provisions pursuant to Article 7 (2) in order to be registered in the register as a radiation physician. Article 7 (5) shall apply mutatis mutandis to an application for registration as referred to in the first sentence.

##### **Article 7b**

1. [This paragraph has not yet entered into force.]
2. Requirements concerning the knowledge, skills and capabilities needed for registration as a general coordinating expert or coordinating expert in the register referred to at (1) shall be laid down by regulation of Our Ministers. Different requirements may be laid down for the various duties.

3. [This paragraph has not yet entered into force.]

#### **Article 7c**

The duties to be performed by a supervisory expert under this Decree shall only be carried out by a person holding a diploma, certificate or other document attesting completion of training in the field of radiation protection obtained from:

- a. an institution recognized by Our Minister as referred to in Article 7f (1); or
- b. an institution or training course recognized or designated by another European Union member state or another state party to the Agreement on the European Economic Area or Switzerland.

#### **Article 7d**

On application Our Ministers shall register in the register referred to in Article 7b (1) a person who is a subject of a state concerned as referred to in Section 1 of the Recognition of EC Professional Qualifications Act if it has been demonstrated under Section 6 of the Recognition of EC Professional Qualifications Act that this person holds qualifications equivalent to the qualifications required by the provisions pursuant to Article 7b (2) in order to be registered in the register as an expert. Article 7b (3) shall apply mutatis mutandis to an application for registration as referred to in the first sentence.

#### **Article 7e**

1. Our Minister shall maintain the register referred to in Article 7b (1) in which a general coordinating expert or coordinating expert is registered.
2. Registration in a register as referred to at (1) may be refused or struck off if the requirements laid down in or pursuant to the Act or in or pursuant to this Decree are not met or not fully met.
3. Rules may be laid down by regulation of Our Ministers and Our Minister of Health, Welfare and Sport on:
  - a. the method of registration;
  - b. the data and documents to be furnished with an application for registration;
  - c. the maximum registration fee;
  - d. the grounds on which and cases in which registration may be refused or struck off;
  - e. the way in which Our Ministers and Our Minister of Health, Welfare and Sport may obtain advice from a designated organization as referred to in Section 69a (1) of the Act on the registration of experts in the register.

#### **Article 7f**

1. Our Minister shall recognize institutions from which persons can obtain a diploma, certificate or other document attesting completion of training in the field of radiation protection.
2. Rules may be laid down by regulation of Our Ministers and Our Minister of Health, Welfare and Sport on:
  - a. requirements concerning applications for recognition;
  - b. requirements concerning the quality of the training;
  - c. requirements concerning examination, assessment and the setting of attainment targets;
  - d. appeal and complaints requirements;
  - e. the way in which Our Ministers and Our Minister of Health, Welfare and Sport may obtain advice on the granting of recognition.
3. A recognition as referred to at (1) shall be published in the Government Gazette.

#### **Article 8**

1. A dosimetry service shall be tasked with supplying personal monitoring devices to the undertaking



for category A or B workers and determining, by reading these monitoring devices, the extent to which the category A or B workers have been exposed to ionizing radiation. This duty shall only be carried out by a service recognized as such by Our Minister. Applying Section 28 (1, last part of sentence) of the Services Act, Section 4.1.3.3 of the General Administrative Law Act shall not apply to an application for recognition referred to in the second sentence.

2. Requirements concerning the quality of service, modus operandi and expertise of the service needed for recognition pursuant to (1) shall be laid down by regulation of Our Minister of Social Affairs and Employment.

#### **Article 9**

1. The undertaking shall ensure that a practice is carried out by or under the supervision of a supervisory expert.
2. The undertaking shall ensure that a supervisory expert working in the undertaking receives adequate continuing education and training in the area of radiation protection.
3. A certain level of expertise and continuing education and training may be required for certain practices by regulation of Our Ministers.
4. The provisions of this Decree concerning expertise apply to practices that are notifiable, or for which a licence is required, under this Decree.
5. The undertaking shall set out in writing the allocation of powers and responsibilities relating to protection against ionizing radiation.

#### **Article 10**

1. The undertaking shall ensure that by or under the supervision of an expert, with a view to protection against ionizing radiation, at least:
  - a. prior to their implementation, plans for practices are examined critically, the risks thereof identified and evaluated and permission granted before the practice is commenced;
  - b. advice is given on protective gear and techniques to ensure the effective protection of persons;
  - c. the effectiveness and correct use of the protective gear and techniques are verified regularly, at least once a year;
  - d. the proper operation and correct use of sources and instruments for measuring ionizing radiation are checked regularly, at least once a year;
  - e. these instruments are regularly calibrated.
2. The undertaking shall ensure that a new or modified source is not taken into service until an acceptance test has been carried out by the expert, followed by his permission to take the source into service.
3. Insofar as protection of exposed workers is concerned, the findings of the expert shall be recorded as part of the risk survey and evaluation referred to in Section 5 of the Health and Safety at Work Act.

#### **Article 11**

1. Following consultation with the expert, the undertaking shall lay down measures to prevent damage and ensure that they are carried out.
2. The undertaking shall ensure in relation to sources, protective gear and measuring instruments that:
  - a. the necessary maintenance is carried out on them;
  - b. the necessary measures are taken to repair or replace inadequate or defective parts thereof, and

- c. sources are taken out of service if necessary.
3. The undertaking shall ensure that the integrity of high-activity sources is checked by or under the supervision of an expert:
    - a. at least once a year and
    - b. after any event in which the source or source holder could have been damaged.
  4. Rules may be laid down by regulation of Our Minister on checking the integrity of high-activity sources.
  5. The undertaking shall ensure in relation to a high-activity source and its associated equipment that by or under the supervision of an expert:
    - a. it is checked whether the source is present at the place where it is being used or has been stored:
      - (i) every three months, if the source is used less than once every three months;
      - (ii) once a year, if the source is used once or more than once every three months;
    - b. it is checked once a year whether the source and the source holder are still in good condition.
  6. Unless otherwise agreed with Our Minister, an undertaking shall immediately send a disused high-activity source to:
    - a. the supplier of the source authorized to receive the source,
    - b. a facility designated pursuant to Article 37 (8) for the receipt of radioactive wastes, or
    - c. another undertaking authorized to receive the source.
  7. The undertaking shall provide funding and facilities for appropriate protection against ionizing radiation to the persons or the radiation protection unit referred to in Article 12 responsible for providing that protection.

#### **Article 11a [To enter into force on 01/01/2015]**

The undertaking shall provide funding and facilities for appropriate protection against ionizing radiation to the general coordinating expert, the coordinating expert, the supervisory expert or the radiation protection unit referred to in Article 12 responsible for providing that protection.

#### **Article 12**

1. Undertakings, types of undertaking or locations at which a radiation protection unit, in which the expert shall also work, shall be present shall be designated, and rules laid down on the duties, powers and modus operandi of a radiation protection unit, by regulation of Our Minister.
2. If a radiation protection unit is required under (1), the undertaking shall ensure that it is operational and at least:
  - a. has sufficient expert persons working in it;
  - b. is functionally and organizationally separate from production and technical units;
  - c. makes recommendations to the undertaking concerning protection against ionizing radiation;
  - d. grants permission for practices.
3. Our Minister may permit a radiation protection unit as referred to at (1) to carry out duties for various undertakings. Applying Section 28 (1, last part of sentence) of the Services Act, Section 4.1.3.3 of the General Administrative Law Act shall not apply to an application for a decision as referred to in the first sentence.

#### **Article 12a**

1. There shall be a radiation incident hotline for notifying radiation incidents, accidents and radiological emergencies.

2. The hotline shall be managed by an authority designated by Our Minister.

### **Article 13**

1. The undertaking shall ensure that a radiation incident, accident or radiological emergency is notified immediately to:
  - (i) the radiation incident hotline; and
  - (ii) the radiation physician concerned, if excessive irradiation or contamination of a category A worker has taken place.
2. The undertaking shall ensure that a practice where it is foreseeable that persons could be unintentionally exposed to excessive external irradiation or excessive internal contamination is only carried out once a coordinating expert or supervisory expert has been consulted on the matter.
3. If in the opinion of a coordinating or supervisory expert the exposure referred to at (2) occurs or is in danger of occurring, the undertaking shall ensure that immediately:
  - a. the practice is discontinued,
  - b. the hazardous places are evacuated, and
  - c. the situation is notified to:
    - (i) the radiation physician concerned, if excessive external irradiation or excessive internal contamination of a worker has taken place; and
    - (ii) the radiation incident hotline.
4. The radiation incident hotline shall inform the authorities designated by regulation of Our Minister as soon as possible of the notifications referred to at (1) and (3).
5. The undertaking shall only discontinue the measures as referred to at (3) (a) or (b) with the agreement of the coordinating expert or the supervisory expert and no sooner than one week after the notification is made in accordance with (3), unless within that time limit the authority that has been informed under (3) or (4) of the notification lays down a different time limit for the discontinuation of the measures.

### **§3.1a. Safety requirements for sources**

#### **Article 14**

1. The undertaking shall ensure that the loss, theft or unintended dispersal of a source is prevented as far as is reasonably possible and that, if a situation of this kind occurs, the undertaking takes all the necessary measures to bring the source back under the undertaking's control or management and to remove any contamination or prevent further exposure of persons.
2. In the case of a practice involving a high-activity source the undertaking shall lay down written instructions to prevent:
  - a. unauthorized access to the source,
  - b. loss or theft of the source, or
  - c. fire damage to the source.
3. The undertaking shall immediately notify the radiation incident hotline of the following situations or measures:
  - a. loss, theft or unintended dispersal of a source;
  - b. an unauthorized practice involving a source,
  - c. the measures taken following:
    - (i) loss or theft of, or an unauthorized practice involving, a source, or
    - (ii) any event in which a source could have been damaged;
  - d. any radiation incident or accident involving a source resulting in unintended exposure of a worker or a member of the public.

4. The undertaking shall ensure that sources are protected against fire as far as is reasonably possible.

#### **Article 14a**

Once practices involving a sealed source have been finally discontinued, the undertaking shall ensure that:

- a. Our Minister is informed thereof as soon as possible, and
- b. the undertaking discards the sealed source within two years of that discontinuation by handing it over to:
  - (i) the person that manufactured or supplied the source,
  - (ii) a person authorized to receive the waste with a view to the use, product re-use or material re-use of radioactive substances or collection of radioactive wastes, or
  - (iii) a facility designated pursuant to Article 37 (6) or (7) or collection service recognized pursuant to Article 37 (8) that is authorized to receive the waste.

#### **Article 14b**

Once practices involving apparatus have been finally discontinued, the undertaking shall ensure that:

- a. Our Minister is informed thereof as soon as possible, and
- b. the undertaking discards the apparatus within two years of that discontinuation by handing it over to:
  - (i) the person that manufactured or supplied the apparatus, or
  - (ii) a person authorized to receive the apparatus with a view to use, product re-use or material re-use, or
- c. the apparatus is scrapped within two years of that discontinuation.

### **§3.2. Information and instruction**

#### **Article 15**

1. The undertaking shall ensure that the person carrying out a practice, and the person managing or supervising this, in relation to the workplace:
  - a. has been adequately instructed concerning the risks associated with ionizing radiation;
  - b. has been informed of the standard methods of protecting against ionizing radiation and the precautions required both for the practice in general and for the duty assigned to him as well as for every workplace where the practice is carried out;
  - c. has been informed of the importance of complying with the technical, health and administrative requirements.
2. If the practice referred to at (1) relates to a high-activity source, instruction shall also be given on:
  - a. the requirements for the safe management of high-activity sources;
  - b. the necessary safety requirements;
  - c. the possible consequences of the omission of appropriate supervision of high-activity sources.
3. The matters listed at (2) shall be set out in writing. This documentation shall be provided to any person carrying out a practice involving a high-activity source and any person managing or supervising this.
4. The instruction on the matters listed at (2) shall be repeated at least every two years.
5. The undertaking shall lay down written instructions on the matters listed at (1) and shall issue these instructions to persons as referred to at (1) and anyone else who could be exposed as a result of the practices.

6. The undertaking shall ensure that the instructions referred to at (5) are written in Dutch or in a language intelligible to the worker concerned. Illustrations or symbols shall be used if necessary instead of written instructions.

#### **Article 16**

The undertaking shall ensure that women who could be exposed to ionizing radiation as a result of a practice are informed before the start of practices about:

- a. the need to give notification of pregnancy at an early stage;
- b. the risks to the unborn child of exposure to ionizing radiation due to external irradiation or contamination;
- c. the risks that a child receiving breastfeeding runs in the event of the mother being contaminated.

#### **Article 17**

The undertaking shall ensure that workers cooperate with the instruction organized for them and comply with the instructions issued to them under this Decree.

### **§3.3. Requirements for apparatus and radioactive substances**

#### **Article 18**

1. The undertaking shall ensure that the rules laid down by regulation of Our Minister concerning apparatus are complied with.
2. This includes at least rules concerning:
  - a. testing apparatus before it is taken into service;
  - b. shielding apparatus against ionizing radiation;
  - c. the positioning of apparatus and the associated ancillary equipment and protective gear;
  - d. the modus operandi of apparatus;
  - e. measures to prevent use of apparatus by unauthorized persons;
  - f. checking the operation of apparatus;
  - h. the environmental dose equivalent rate that apparatus is permitted to cause;
  - (i) requirements that must be met by a person using the apparatus.

#### **Article 19**

1. The undertaking shall ensure that the rules laid down by regulation of Our Minister concerning sealed sources are complied with.
2. This includes at least rules concerning:
  - a. measures upon arrival of the source at the location;
  - b. requirements concerning the construction and packaging of the source;
  - c. measures to prevent use of a source by unauthorized persons;
  - d. checking the operation of a source;
  - e. the environmental dose equivalent rate that a source is permitted to cause;
  - f. performance of a leakage or contamination test;
  - g. requirements that must be met by a person using the source.

#### **Article 20**

1. The undertaking shall ensure that, in situations where the doses set out in Article 49 or 76 could be exceeded as a result of practices, effective clear warning signs or symbols and inscriptions are displayed at suitable places.
2. The undertaking shall ensure that areas and places where practices involving open sources are

carried out, their furnishings and fittings or objects used there are regularly checked for contamination in accordance with procedures laid down by the undertaking in writing.

3. The undertaking shall ensure that, if this is reasonably possible, open and sealed sources are stored in a suitable storage facility when not in use.
4. Rules may be laid down by regulation of Our Minister of Social Affairs and Employment concerning the model for, inscriptions on and minimum size of the warning signs or symbols referred to at (1), and where and in what way they must be displayed.

### **§3.3a. Requirements for high-activity sources**

#### **Article 20a**

1. The manufacturer shall engrave or stamp on every high-activity source manufactured by it a code made up as follows:
  - a. the designation 'NL',
  - b. followed by a standard code assigned to the manufacturer by Our Minister,
  - c. followed by a code in Roman letters or Arabic numerals identifying the source, to be determined by the manufacturer.
2. An application for assignment of the code referred to at (1) (b) shall be submitted to Our Minister. The application shall include the numbers of the licences granted to the applicant pursuant to Section 15 (a) or 29 (1) of the Act.
3. Paragraph 1 does not apply if the dimensions of the source are too small for the procedure referred to at (1) to be carried out.
4. The manufacture shall also engrave the code referred to at (1) on the source holder of the source concerned or stamp that code on that source holder.
5. Paragraph 4 does not apply if the dimensions of the source holder are too small for the procedure referred to at (1) to be carried out or if the source holder is intended for re-use as casing for a source. In the latter case the manufacturer shall provide information concerning at least the nature of the high-activity source on the source holder.
6. The manufacturer shall provide information concerning the nature of the high-activity source on the source container.
7. The manufacturer of a high-activity source shall ensure that:
  - a. the source is accompanied by:
    - (i) written information confirming that the source complies with (1) and the rules laid down pursuant to Article 20 (4) concerning the source or the source holder;
    - (ii) colour photographs of the design of the source and the associated source holder and, insofar as applicable, of the design of the associated source container and the associated equipment;
  - b. on delivery of the source, the information and photographs referred to at (a) are furnished to the person to whom the source is supplied;
  - c. the code referred to at (1) and (4) and the warning symbols and inscriptions displayed on the source, source holder or source container pursuant to Article 20 (4) remain as legible as possible.

#### **Article 20b**

1. The manufacturer shall engrave or stamp on the source holder of every high-activity source to be supplied by it a code made up as follows:
  - a. the designation 'NL',

- b. followed by a standard code assigned to the manufacturer by Our Minister,
- c. followed by a code in Roman letters or Arabic numerals identifying the source, to be determined by the manufacturer.

2. Paragraph 1 does not apply if:

- a. the code referred to in Article 20a (1), or another unique code in Roman letters or Arabic numerals is already displayed on the source holder of a high-activity source;
- b. the dimensions of the source holder are too small for the procedure referred to at (1) to be carried out, or this holder is intended for re-use as casing for a source.

3. In the case referred to at (2) (b), Article 20a (5, second sentence) shall apply mutatis mutandis.

4. Article 20a (2), (6) and (7) shall apply mutatis mutandis.

#### **Article 20c**

Article 20b (1)-(3) and Article 20a (2), (6) and (7) (a) and (c) shall apply mutatis mutandis to an undertaking carrying out a practice involving a high-activity source.

#### **Article 20c**

Our Minister may lay down rules on security for the holding of radioactive substances designed for practices for which a licence is required under Article 24 or Article 25.

### **§3.4. Financial security for high-activity sources**

#### **Article 20d**

1. The undertaking shall furnish financial security to cover the cost of meeting the obligations upon the undertaking in relation to the safe removal of a disused high-activity source in the event of:

- a. the undertaking going bankrupt or otherwise discontinuing its business activities;
- b. the person with whom an agreement was concluded to receive the disused high-activity sources is no longer in a position to receive them.

2. The financial security shall be furnished in one or more of the following forms:

- a. a suretyship or bank guarantee,
- b. an insurance agreement,
- c. participation in a fund set up for this purpose that in the opinion of Our Minister and Our Minister of Finance provides an adequate safeguard that the cost referred to at (1) will be covered;
- d. any other arrangement whereby the financial security in the opinion of Our Ministers and Our Minister of Finance provides an adequate safeguard that the cost referred to at (1) will be covered.

3. A minimum sum for which financial security is to be furnished per unit of volume of source to be removed and for the associated source holder and the fixed shielding shall be laid down by regulation of Our Minister.

4. The financial security shall be payable to the State of the Netherlands.

#### **Article 20e**

The financial security shall be maintained until such time as the high-activity source for which the financial security is furnished:

- a. is transferred by the undertaking to another undertaking that has furnished the financial security required for that source,

- b. is handed over by the undertaking to a radioactive waste collection service recognized pursuant to Article 37 (7), or
- c. is handed over by the undertaking to a facility designated pursuant to Article 37 (8) for the receipt of radioactive wastes.

#### **Article 20f**

1. Before acquiring a high-activity source, the undertaking shall furnish Our Minister with:
  - a. information on the volume of the source, source holder and fixed shielding of that source acquired;
  - b. written proof that the financial security required pursuant to Article 20d (1) has been furnished.
2. Paragraph 1 does not apply if the data referred to therein has already been furnished with an application for a licence for a practice as referred to in Articles 24 and 25 (1).
3. Further requirements may be laid down by regulation of Our Minister concerning the data to be furnished.

#### **§3.5. Charges for storage of radioactive waste**

#### **Article 20g**

The licensee shall determine the charges that the licensee makes for maintaining in operation a facility at which fuels are stored as referred to in Section 15 (b) of the Act, as designated by Our Minister under Article 37 (8), in a transparent, objective and non-discriminatory manner. The charges shall include the costs incurred by the licensee for research and development for the management of radioactive wastes as included in the national programme referred to in Article 20h.

#### **Part 3a: National Programme**

#### **Article 20h**

1. Our Minister shall establish a programme as referred to in Article 5 (1) (a) of Directive 2011/70/Euratom for the management of radioactive wastes.
2. The programme will be based on the following principles:
  - a. limiting the creation of radioactive wastes to the minimum that is practically feasible, in terms of both activity and volume;
  - b. the interdependencies between all the steps in the creation and management of radioactive wastes;
  - c. the safe management of radioactive wastes;
  - d. the adoption of passive safety measures for the long term;
  - e. a graded approach to the implementation of the measures;
  - f. the cost of managing radioactive wastes shall be borne by the person that caused these wastes to be created;
  - g. an empirically based and documented decision-making process at all the stages in the management of radioactive wastes.
3. The programme will also include:
  - a. the policy objective regarding the management of all types of radioactive wastes;
  - b. the milestones required for the implementation of the programme and the timeframe for achieving these milestones;
  - c. the identification of all the radioactive wastes and estimates of future quantities;
  - d. concepts, plans and technical solutions for the management of radioactive wastes, from creation to disposal;
  - e. concepts or plans for the period following the closure of a facility for geological disposal;
  - f. research, development and demonstration activities needed to apply solutions for the



- management of radioactive wastes;
- g. the responsibility for implementation of the programme and the key performance indicators for monitoring progress towards implementation;
- h. an assessment of the costs of the national programme and the basis and hypotheses underlying this assessment, including a profile over time;
- (i) the financing schemes for implementation of the programme;
- j. the policy on the furnishing of information on the management of radioactive wastes to workers and the public;
- k. an overview of agreements concluded with other member states and third countries on the management of radioactive wastes.

## **Part 4: Notifications, Licences, Applications and Procedures**

### **§4.1. Notifications of practices involving apparatus and radioactive substances**

#### **Article 21**

1. An undertaking carrying out a practice involving apparatus or a radioactive substance shall give notification of this at least three weeks before the commencement of that practice.
2. This obligation does not apply if it is a practice involving:
  - a. apparatus or a radioactive substance for which a licence is required under this Decree;
  - b. an electron beam tube for display of visual images;
  - c. apparatus other than referred to at (a) or (b) with a maximum high tension of no more than 30 kV that under normal operating conditions does not cause an environmental dose equivalent rate higher than 1  $\mu$ Sv per hour at 0.1 metres from any accessible external surface of the apparatus;
  - d. apparatus other than referred to at (a), (b) or (c) that under normal operating conditions does not cause an environmental dose equivalent rate higher than 1  $\mu$ Sv per hour at 0.1 metres from any accessible external surface of the apparatus and that is of a type approved by Our Minister under rules laid down by regulation of Our Minister.
3. The obligation referred to at (1) does not apply to practices involving sources if the practices with these sources have already been notified in the application for a licence for a practice as referred to in Articles 23 (1) and (2), 24, 25 (1), 35 (1) and 37 (1) or in the annual report for this licence.

#### **Article 22**

If practices involving apparatus or a radioactive substance notified in accordance with Article 21 are discontinued, the undertaking shall give notification thereof as soon as possible after the discontinuation of the practice.

### **§4.2. Licences for practices**

#### **Article 23**

1. Without a licence from Our Minister it is prohibited to carry out a practice involving:
  - a. apparatus for:
    - (i) industrial radiography;
    - (ii) processing of products;
    - (iii) educational purposes;
    - (iv) exposure of persons and animals for therapeutic purposes;
  - b. apparatus other than referred to at (a) with a maximum high tension of 100 kV or more;
  - c. apparatus that accelerates particles and is capable of emitting ionizing radiation with an energy of more than 1 MeV.
2. Without a licence from Our Minister it is also prohibited to carry out research and development work on apparatus.

3. The prohibition referred to at (1) does not apply to:
- a. practices involving electron microscopes;
  - b. solely storing apparatus for the purpose of trading that apparatus;
  - c. apparatus used for educational purposes that under normal operating conditions does not cause an environmental dose equivalent rate higher than 1  $\mu\text{Sv}$  per hour at 0.1 metres from any accessible external surface of the apparatus and that is of a type approved by Our Minister under rules laid down by regulation of Our Minister;
  - d. practices involving apparatus designed and used for the following applications:
    - (i) veterinary diagnosis, solely insofar as veterinary applications are concerned, using apparatus with only a vertical downward-focused beam with a fixed focus film distance;
    - (ii) X-ray diffraction or spectrography carried out in a closed safety cabinet;
    - (iii) baggage inspection using a fixed setup, with the exception of apparatus that accelerates particles and is capable of emitting ionizing radiation with an energy of more than 1 MeV;
    - (iv) quality control of foods and other products.

#### Article 24

Without a licence from Our Minister it is prohibited:

- a. to administer radioactive substances to persons and, insofar as protection of humans against ionizing radiation is concerned, to animals for:
  - (i) making medical or veterinary diagnoses;
  - (ii) therapy or medical/biomedical research;
- b. adding radioactive substances to products designed for use on or in the immediate environs of persons;
- c. carrying out practices involving radioactive substances for:
  - (i) industrial radiography;
  - (ii) processing of products;
  - (iii) educational purposes and scientific research.

#### Article 25

1. Without a licence from Our Minister it is prohibited to carry out a practice other than referred to in Article 24 or 37, other than a discharge, involving a radioactive substance.
2. The prohibition referred to at (1) and in Article 24 (c) does not apply if at a location:
  - a. the activity of the radionuclides in the radioactive substance concerned is lower than the value laid down pursuant to Article 3 (1, opening) and (c),
  - b. the activity concentration of the substance is lower than the value laid down pursuant to Article 3 (1, opening) and (c), or
  - c. a practice is carried out involving:
    - (i) a nickel-63 source that forms part of analytical equipment with a maximum activity of 1 GBq, or
    - (ii) a measuring, control or calibration source in a fixed setup with an activity of the nuclide used of less than 100 times the activity of the value laid down therefor pursuant to Article 3.
3. If a radioactive substance contains multiple types of radionuclides, the activity concentration of the radionuclides shall be weighted and aggregated using the method to be designated by regulation of Our Minister. The requirements of 2 (b) have been met if the result of this aggregation is less than or equal to 1.
4. If multiple practices take place at a location at any time, the activities of the radionuclides in the radioactive substances involved in those practices shall be weighted and aggregated using the method to be designated by regulation of Our Minister. The requirements of 2 (a) have been met if the result of this aggregation is less than or equal to 1.
5. Practices involving products as referred to in Article 24 (b) where the radionuclides added to these products shall not be included in aggregation as referred to at (3) may be designated by regulation

of Our Minister.

6. The prohibitions referred to at (1) and in Articles 23 and 24 do not apply to practices designated by regulation of Our Minister that entail a limited risk of exposure of humans.
7. Other methods may be designated by regulation of Our Minister for determining and assessing damage in cases where the activity concentration referred to at (2) combined with the activity referred to at (2) does not give a correct indication of the damage that the radioactive substances involved in the practice could cause.
8. Notwithstanding (2), paragraph 1 may be declared applicable by regulation of Our Minister if there is an excessively high risk of exposure of workers and members of the public.

#### **Article 26**

1. The prohibition referred to in Article 25 (1) also does not apply to practices involving a sealed source where the values laid down pursuant to Article 3 (opening) and (c) for the activity and the activity concentration are exceeded, if:
  - a. it is of a type approved by Our Minister, and
  - b. under normal operating conditions it does not cause an environmental dose equivalent higher than 1  $\mu$ Sv per hour at 0.1 metres from any accessible external surface thereof.
2. Rules may be laid down by regulation of Our Minister concerning type approval as referred to at (1) (a) and for the storage and removal of sealed sources as referred to at (1).

#### **§4.3. Indicators**

##### **Article 27**

Notwithstanding Articles 24 (b) and 25, it is prohibited:

- a. to add radionuclides to an indicator for illumination purposes;
- b. to carry out practices involving an indicator to which radionuclides have been added for illumination purposes.

##### **Article 28**

The prohibitions in Articles 24 (b) and 27 do not apply if:

- a. an indicator is concerned;
- b. solely H-3 (in lighting cells) or Pm-147 (in luminous paint) is or has been added for illumination purposes;
- c. the indicator has a total activity lower than 1 GBq H-3 or 10 MBq Pm-147;
- d. the indicator complies with construction requirements laid down by regulation of Our Minister in the interests of protection against ionizing radiation;
- e. the marks or warning symbols designated by regulation of Our Minister are displayed on the indicator;
- f. repair and maintenance work on the indicator is carried out in accordance with rules laid down by Our Minister; and
- g. no more than 500 indicators to which H-3 in lighting cells or Pm-147 in luminous paint has been added are held.

##### **Article 29**

1. It is prohibited to hold indicators manufactured outside the Netherlands to which radionuclides have been added for illumination purposes with the purpose of placing them on the Dutch market if these indicators do not comply with the rules laid down in or pursuant to Articles 27 and 28.
2. Our Minister of Defence may grant exemption from the prohibitions laid down in Articles 24 (b), 25

(1) and 27 in the case of indicators to which radionuclides have been added for illumination purposes and that are in use or designed for use in the armed forces and that are intended for use under operational conditions.

3. Further rules concerning indicators may be laid down by regulation of Our Minister.

Article 30 [Repealed with effect from 01/01/2014]

Article 31 [Repealed with effect from 01/01/2014]

Article 32 [Repealed with effect from 01/01/2014]

Article 33 [Repealed with effect from 01/01/2014]

Article 34 [Repealed with effect from 01/01/2014]

#### **§4.4. Licences and requirements concerning the discarding of radioactive substances**

##### **Article 35**

1. Without a licence from Our Minister it is prohibited to discard radioactive substances by discharging them into the air, into a public sewer or into surface water.
2. This prohibition does not apply if:
  - a. in the case of discharge into the air, the activity of the total amount of radioactive substances discharged in a calendar year on leaving the location via a discharge point is lower than 1 radiotoxicity equivalent for inhalation as referred to in the Annex;
  - b. in the case of discharge into a public sewer, the activity of the total amount of radioactive substances discharged in a calendar year on leaving the location via a discharge point is lower than 10 radiotoxicity equivalents for ingestion as referred to in the Annex;
  - c. in the case of discharge into surface water, the activity of the total amount of radioactive substances discharged in a calendar year on leaving the location via a discharge point is lower than 0.1 radiotoxicity equivalents for ingestion as referred to in the Annex;
3. It is prohibited to discharge radioactive substances onto or into the ground.
4. The prohibition referred to at (3) does not apply to discharge into the ground if the total amount of radioactive substances discharged in a calendar year on leaving the discharge point is lower than  $10^{-6}$  radiotoxicity equivalents for ingestion as referred to in the Annex.
5. The prohibition referred to at (3) does not apply to the discharge of production water in mining if this takes place by means of injection into a similar soil formation and depth as that from which the water originated and in such a way that the water does not enter other water-bearing strata.
6. The amounts discharged, expressed in radiotoxicity equivalents, shall be corrected for physical decay using correction factors as set out in the Annex.

##### **Article 36**

1. An undertaking carrying out a practice shall ensure that, as far as is reasonably possible:
  - a. the creation of radioactive wastes is prevented or limited,
  - b. sources are re-used as such after use,
  - c. radioactive substances and materials comprising a source are re-used after their use, or
  - d. objects, substances and materials contaminated or activated with radioactive substances are processed after use in such a way that they can be re-used.
2. When manufacturing sources, use shall be made of substances and materials that after use of the

source cause as few as possible harmful effects on the environment or none.

3. The undertaking shall ensure that a practice is carried out as far as possible in a way that guarantees protection against damage.

#### **Article 37**

1. Without a licence from Our Minister it is prohibited to discard radioactive substances for product re-use or material re-use or radioactive wastes.
2. This prohibition does not apply if:
  - a. the total activity of the radionuclides in the radioactive substances concerned in a calendar year is lower than the value laid down for those radioactive substances pursuant to Article 3 (1, opening) and (c), or
  - b. the activity concentration of that substance is lower than the value laid down therefor pursuant to Article 3 (1, opening) and (c).
3. Article 25 (3), (4), (6) and (7) shall apply mutatis mutandis.
4. Without prejudice to the provisions of Article 11 (6), the prohibition also does not apply in the case of sealed sources that are taken back by the person who manufactured or supplied the source.
5. The prohibition also does not apply in the case of actual delivery of radioactive substances by mere handover to a third party with a view to:
  - a. product or material re-use of radioactive substances, or
  - b. collection of radioactive wastes.
6. The prohibition also does not apply to handover to a facility designated by Our Ministers for the receipt of seized radioactive substances as referred to in Section 33 (4) of the Act.
7. The prohibition also does not apply to the discarding of radioactive wastes by means of handover to a radioactive waste collection service recognized by Our Minister.
8. The prohibition also does not apply to handover to facilities designated by Our Minister for the receipt of radioactive wastes.
9. Paragraphs 4-8 apply only if the undertaking has ascertained that the recipient holds a licence for the practice concerned or is otherwise authorized to receive these substances.
10. Applying Section 28 (1, last part of sentence) of the Services Act, Section 4.1.3.3 of the General Administrative Law Act shall not apply to an application for designation as referred to at (6) and (8) and an application for recognition as referred to at (7).

#### **Article 38**

1. A radioactive substance may be designated as a radioactive waste by Our Minister or the undertaking if no use or product or material re-use is foreseen for that material by that Minister or the undertaking and there is no question of discharging the substance.
2. A waste shall not be designated as a radioactive waste if Article 37 (2) applies.
3. Radioactive waste shall be removed as soon as is reasonably possible.
4. The obligation laid down at (3) does not apply if the radioactive wastes have a physical half-life of less than 100 days and are stored for a maximum of two years in a suitable area with a view to physical decay into wastes as referred to in Article 37 (2).
5. It is prohibited to mix radioactive wastes for the purpose of bringing the activity concentration of the

wastes below the value laid down pursuant to Article 3 (1, opening) and (a).

#### **§4.5. Refusal of licence**

##### **Article 39**

No licence pursuant to this Part shall be granted if:

- a. the requirements in Articles 4, 5, 6, 9, 10, 11, 12, 48, 76, 77 and 78 concerning justification, expertise, optimization and dose limits have not been met;
- b. one of the following doses is exceeded in the case of a member of the public outside the location as a result of the practice in respect of which the licence has been applied for and as a result of other practices inside and outside this location:
  - (i) an effective dose of 1 mSv in a calendar year, and taking this into account:
  - (ii) an equivalent dose of 50 mSv in a calendar year for the skin, averaged over any skin area of 1 cm<sup>2</sup>;
- c. the practice in respect of which the licence has been applied for is in a category declared as justified under the Ministerial Regulation referred to in Article 4 (2) but the specific nature of this practice is not justified under Article 4 (1);
- d. it has not been demonstrated that the financial security required pursuant to Article 20d (1) has been furnished.

##### **Article 39a**

Without prejudice to Sections 18a, 31 (4) and 34 (7) of the Act, a licence granted pursuant to this Part may be withdrawn in whole or in part if no practices are carried out using the licence for two years.

#### **§4.6. Procedural requirements for notifications**

##### **Article 40**

1. The undertaking shall make notifications as referred to in Articles 21, 22 and 103 to Our Minister.
2. Further rules may be laid down by regulation of Our Minister concerning notifications as referred to at (1).

Article 41 [Repealed with effect from 01/01/2014]

Article 42 [Repealed with effect from 01/01/2014]

#### **§4.7. Procedural requirements for licences**

##### **Article 43**

1. Further rules may be laid down by regulation of Our Minister concerning applications for a licence for a practice as referred to in Articles 23 (1) and (2), 24, 25 (1), 35 (1), and 37 (1).
2. An application as referred to at (1) shall not be for practices carried out at the location by the person holding a licence for carrying out the practices concerned at constantly changing places.

##### **Article 44**

1. Once a licence has been granted, the holder thereof shall inform Our Minister of any change in any of the data given when applying for it.
2. Further rules may be laid down by regulation of Our Minister concerning data for licence applications.

#### **§4.8. Preparatory procedure**

## **Article 45**

Part 3.4 of the General Administrative Law Act and Part 13.2 of the Environmental Management Act shall apply to the preparatory procedure for a decision in respect of a licence as referred to in Article 23 (1) (c), unless:

- a. the apparatus is designed solely for radiological procedures;
- b. the apparatus is located in a vehicle or on board a vessel or aircraft that is used as such;
- c. the apparatus is located at constantly changing locations and in the opinion of Our Minister the interests of applying Part 3.4 of the General Administrative Law Act and Part 13.2 of the Environmental Management Act are outweighed by the disadvantages;
- d. if a licence has previously been granted for apparatus of the same type for the same place and in the opinion of Our Minister it is not expected that more damage could occur as a result of using the licence requested than that taken into consideration when granting the previous licence.

## **Article 46**

1. Part 3.4 of the General Administrative Law Act and Part 13.2 of the Environmental Management Act shall not apply to the preparatory procedure for a decision in respect of a licence for practices involving open sources if the result of the weighted aggregation of the activities of the amounts of radionuclides present at any time in the radioactive substances involved in those practices does not exceed  $10^4$  using the method designated in the regulation referred to in Article 3 (1, opening) and (a).
2. Paragraph 1 shall apply mutatis mutandis to sealed sources, subject to the proviso that that result shall not exceed  $10^7$ .

## **Article 47**

1. If Part 3.4 of the General Administrative Law Act applies to the preparatory procedure for a decision on a licence for a practice involving radioactive substances, the following shall be involved, other than as advisers: the provincial executive of the province, the municipal executive of the municipality where the practice is being or is to be carried out or, in the case of a discharge into surface waters, the authority responsible for quality management of the surface water into which the discharge is taking or is to take place.
2. If Part 3.4 of the General Administrative Law Act applies to the preparatory procedure for a decision on a licence for a practice involving apparatus, the municipal executive of the municipality where the practice is being or is to be carried out shall be involved, other than as an adviser.
3. Our Minister shall announce decisions on applications for licences to whose preparatory procedure Part 3.4 of the General Administrative Law Act does not apply in the Government Gazette.

## **Article 47a**

Applying Section 28 (1, last part of sentence) of the Services Act, Section 4.1.3.3 of the General Administrative Law Act shall not apply to an application for a licence referred to in Articles 23 (1) and (2), 24, 25 (1), 35 (1), and 37 (1).

## **Part 5: Public exposure**

### **Article 48**

1. The undertaking shall ensure that as a result of practices carried out under the undertaking's responsibility an effective dose of 0.1 mSv in one calendar year is not exceeded for a member of the public at any point outside the location.
2. This Article does not apply to persons granting aid and assistance as referred to in Article 53 (2).

## **Article 49**

1. The undertaking shall ensure that the following individual doses are not exceeded for a member of the public inside the location as a result of practices carried out under the undertaking's responsibility:
  - a. an effective dose of 1 mSv in a calendar year, and taking this into account:
  - b. an equivalent dose of:
    - (i) 15 mSv in a calendar year in the lens of the eye, or
    - (ii) 50 mSv in a calendar year for the skin, averaged over any skin area of 1 cm<sup>2</sup>.
2. In the case of internal contamination the committed effective dose shall be assigned to the year of intake.
3. This Article does not apply to persons granting aid and assistance as referred to in Article 53 (2).

## **Article 50**

1. The undertaking shall ensure that in circumstances where a member of the public could be exposed to contamination or ionizing radiation inside or outside the location as a result of practices carried out under the undertaking's responsibility, calculations of the effective or equivalent doses are made for the places concerned, and if necessary measurements carried out.
2. The undertaking shall keep records in which the undertaking notes the results of the measurements and calculations and shall if necessary use these to determine the doses referred to at (1) and in Articles 48 and 49.
3. Further rules may be laid down by regulation of Our Minister concerning the content, management and retention period of the records.

## **Article 51**

In the event of an accident or radiological emergency at its location, the undertaking shall ensure that if a member of the public inside or outside the location concerned has been or could be exposed as a result thereof, individual monitoring is carried out or the effective or equivalent doses received by the person concerned are determined in some other way.

## **Part 6: Medical applications of radiation and radiation protection**

### **§6.1. Definitions and Scope**

#### **Article 52**

In this Part and the provisions based upon it the following terms are defined as follows:

- a. equipment: apparatus, sealed sources and open sources and associated equipment such as film processors, diagnostic monitors, PET/CT scanners and gamma cameras;
- b. attending physician: a medical doctor or dentist under whose medical responsibility exposure to ionizing radiation takes place;
- c. health screening programme: study among at-risk groups in the population in which ionizing radiation is used with the aim of making an early diagnosis;
- d. diagnostic reference levels: dose levels in medical radiodiagnosis and where radiopharmaceuticals are used, amounts of radioactivity to be administered, for characteristic studies of groups of patients of standard size or standard phantoms for broadly defined types of apparatus or devices;
- e. quality assurance: the planned and systematic procedures required to provide adequate certainty that a structure, system, component or procedure functions satisfactorily and in line with generally accepted standards;
- f. medical radiological procedure: the procedure from request up to and including the carrying-out of and consideration of the results of the radiological procedure;



- g. medical examination for legal purposes: radiological procedure that is not medically indicated, solely for the purpose of insurance or legal purposes;
- h. medical responsibility: the responsibility of a medical doctor or dentist for individual radiological procedures, in particular their justification, optimization and clinical evaluation of the results;
- (i) patient dose: the dose relating to a person undergoing exposure as referred to in Article 53 (1);
- j. practical aspects: the actual carrying-out of exposure as referred to in Article 53 (1), including: handling and using radiological equipment, assessing technical physical parameters, and assessing patient doses, calibration, maintenance of equipment, preparation and administration of radiopharmaceuticals, and processing of films;
- k. radiodiagnostic: relating to in vivo diagnostic nuclear medicine, diagnostic radiology and dental radiology;
- l. radiological: relating to radiodiagnostic and radiotherapeutic procedures and interventional radiology or other radiology for planning or guidance purposes;
- m. radiotherapeutic: relating to radiotherapy, including nuclear medicine for therapeutic purposes;
- n. referrer: a medical practitioner, including at least medical doctors, dentists, nursing specialists and physician assistants, requesting a procedure involving the use of ionizing radiation.

### **Article 53**

1. This Part applies to radiological procedures on persons:
  - a. undergoing exposure as patients;
  - b. taking part in a health screening programme;
  - c. undergoing an occupational medicine examination;
  - d. undergoing a medical examination for legal purposes;
  - e. voluntarily taking part in medical or biomedical research programmes.
2. This Part also applies to persons who knowingly – other than as part of their occupation – provide aid and assistance to those undergoing exposure as referred to at (1).

### **§6.2. Radiological procedures**

#### **Article 54**

1. The undertaking shall ensure that a radiological procedure is carried out solely under the medical responsibility of an attending physician who:
  - a. meets expertise requirements laid down by regulation of Our Minister of Health, Welfare and Sport, and
  - b. other than in the case of a dentist, is registered in the register of medical specialists set up pursuant to Section 14 of the Individual Health Care Occupations Act.
2. The expertise referred to at (1) (a) shall be obtained from a recognized institution as referred to in Article 7c (a) or a recognized or designated institution or training course as referred to in Article 7c (b).

#### **Article 55**

1. A type of radiological procedure is not justified if the total possible diagnostic or therapeutic benefit, including the direct benefit to the health of the person undergoing the exposure, and the social benefit are outweighed by the health detriment that the person undergoing the exposure could experience, taking into account the effectiveness, benefits and risks of available alternative techniques that have the same aim but involve less exposure or none.
2. What types of radiological procedures that do not justify exposure under (1) are prohibited may be laid down by regulation of Our Minister of Health, Welfare and Sport.

#### **Article 56**

1. The referrer and the attending physician, each on the basis of their specific responsibility, shall

assess whether an individual radiological procedure is justified, taking into account the specific aims of the exposure and the characteristics of the person concerned.

2. Notwithstanding Article 55 (2), a radiological procedure prohibited under that paragraph may nevertheless be justified in special circumstances, as assessed on a case-by-case basis. The individual assessment of the aforementioned justification shall be recorded in the person's medical record.
3. An attending physician shall not permit exposure of a person referred to in Article 53 (2) if this does not yield sufficient benefit, taking into account the damage to the health of the person undergoing the exposure, the direct benefit to the health of the person referred to in Article 53 (1), the social benefit and the health detriment that the exposure could cause.

#### **Article 57**

The undertaking shall ensure that the attending physician pays special attention to the justification of:

- a. medical examination for legal purposes;
- b. medical and biomedical research.

#### **Article 58**

The undertaking shall ensure that in the case of exposure as referred to in Article 53 (1) the target volumes to be irradiated for radiotherapeutic purposes are individually planned in line with sound clinical physics, taking into account the fact that the patient dose in the tissue outside the target volume should be as low as is reasonably possible without adversely affecting the intended radiotherapeutic effect of the exposure.

#### **Article 59**

Our Minister of Health, Welfare and Sport shall promote the establishment and use of diagnostic reference levels for radiodiagnostic procedures as referred to in Article 53 (1) and the drawing-up of protocols on the subject.

#### **Article 60**

The undertaking shall ensure that, without prejudice to the provisions of the Medical Research (Human Subjects) Act:

- a. a patient dose constraint is laid down for trial subjects who cannot themselves expect any direct benefit from the radiological procedure;
- b. if the experimental radiological procedure is intended to produce a benefit for trial subjects, the planning of the experimental procedure is targeted to the trial subject.

#### **Article 61**

1. Our Minister of Health, Welfare and Sport may lay down dose constraints for exposures as referred to in Article 53 (2).
2. Rules may be laid down by regulation of Our Minister of Health, Welfare and Sport, in agreement with Our Minister, on the exposures referred to at (1).

#### **Article 62**

The undertaking shall ensure that in the event of a person undergoing examination or treatment using administered radionuclides, the person or his statutory representative is given written instructions where necessary. They shall also be informed of the risks of the ionizing radiation before the person concerned leaves the location, so as to limit the dose to others who come into contact with this person as far as is reasonably possible.

### **§6.3. Requirements for equipment**

#### **Article 63**

The undertaking shall ensure that:

- a. persons receiving training in the field of applications of radiation and radiation protection participate in modules on practical aspects thereof;
- b. if the aforementioned participation takes place under the responsibility of a medical doctor, that this is a medical doctor as referred to in Article 54;
- c. prior to the participation referred to at (a), written instructions are given to the person receiving the training on the nature and extent of the participation in the practical aspects.

#### **Article 64**

1. The undertaking shall ensure that the activity to be administered in nuclear medicine examination and therapy is measured using a dose calibrator.
2. Our Minister of Health, Welfare and Sport may designate standards for the accuracy of the calibrator referred to at (1).

#### **Article 65**

The undertaking shall ensure that written protocols are drawn up for every standard radiological procedure for every equipment setup.

#### **Article 66**

The undertaking shall ensure that:

- a. a clinical physicist is closely involved in radiotherapeutic procedures;
- b. in the case of standard therapeutic nuclear medicine procedures and diagnostic nuclear medicine procedures a clinical physicist is available;
- c. in the case of other radiological procedures a clinical physicist is on call to provide advice on radiation protection aspects of radiological procedures.

#### **Article 67**

1. The undertaking shall ensure that the radiological equipment used in radiological procedures is used in a responsible manner. Our Minister of Health, Welfare and Sport may lay down rules to this end.
2. The undertaking shall ensure that in the case of all radiological equipment in use:
  - a. rigorous supervision is exercised as regards radiation protection;
  - b. quality assurance programmes are carried out;
  - c. the necessary measures are taken to repair or replace inadequate or defective parts of radiological equipment.

#### **Article 68**

The undertaking shall ensure that:

- a. if new equipment is taken into service, if feasible it has a facility for indicating the radiation dose during a radiological procedure;
- b. in the case of X-ray apparatus used to carry out radiodiagnostic procedures, a filter is used to limit the patient's radiation exposure;
- c. X-ray apparatus has a fixed or automatic diaphragm setting so that the edges of the X-ray beam are visible on the image medium, except in the case of mammography or dental examination;

- d. X-ray apparatus used to carry out radiodiagnostic procedures is fitted with a diaphragm or tube for the purpose of limiting the X-ray beam to the correct area;
- e. the diaphragm has a means of giving prior indication of the beam dimensions.

#### **Article 69**

The undertaking shall ensure that:

- a. in the case of examinations using fluoroscopy an image amplifier or equivalent technique is used;
- b. fluoroscopic examinations without facilities for regulating the dose rate are confined to cases where these circumstances are justified;
- c. apparatus suitable for radiography provides an acoustic signal after every five minutes of cumulative irradiation.

#### **Article 70**

The undertaking shall ensure that appropriate radiological equipment, techniques and ancillary equipment are used for radiological procedures in the case of:

- a. children;
- b. health screening programmes;
- c. administration of a high dose of ionizing radiation to a patient.

#### **Article 71**

Before carrying out a radiological procedure the referrer and the attending physician shall ascertain in the case of a woman whether she is pregnant and whether she is breastfeeding.

#### **Article 72**

If pregnancy cannot be ruled out or the woman is breastfeeding, depending on the type of exposure special attention shall be paid to:

- a. the justification of the exposure, especially in connection with urgency;
- b. optimizing the radiation protection, taking into account the patient dose for both the woman and the unborn child.

#### **Article 73**

1. The undertaking shall ensure that both the likelihood and consequences of an accident or an unintended dose from a radiological procedure are as small as is reasonably possible.
2. The undertaking shall ensure that written instructions and protocols are present with the equipment to limit risks as referred to at (1).

#### **Article 74**

1. The undertaking shall furnish Our Minister of Health, Welfare and Sport with the data required to enable the average and spread of the effective or equivalent dose in the population and other relevant reference groups from radiological procedures to be estimated.
2. Our Minister of Health, Welfare and Sport shall lay down rules on the furnishing of the data referred to at (1).

#### **Article 75**

Our Minister of Health, Welfare and Sport may lay down rules to prevent the unnecessary spread of radiological equipment.

## **Part 7: Occupational Exposure**

### **§7.1. Dose limits and classification of workers**

#### **Article 76**

1. The undertaking shall ensure that the following doses are not exceeded for workers as a result of practices carried out under the undertaking's responsibility:
  - a. an effective dose of 1 mSv in a calendar year, and taking this into account:
  - b. an equivalent dose of:
    - (i) 15 mSv in a calendar year for the lens of the eye, or
    - (ii) 50 mSv in a calendar year for the skin, averaged over any exposed skin area of 1 cm<sup>2</sup>.
2. In the case of internal contamination the committed effective dose shall be assigned to the year of intake.

#### **Article 77**

1. The undertaking shall ensure that the following doses are not exceeded for workers exposed as a result of practices carried out under the undertaking's responsibility:
  - a. an effective dose of 20 mSv in a calendar year, and taking this into account:
  - b. an equivalent dose of:
    - (i) 150 mSv in a calendar year for the lens of the eye,
    - (ii) 500 mSv in a calendar year for the skin, averaged over any exposed skin area of 1 cm<sup>2</sup>, or
    - (iii) 500 mSv in a calendar year for hands, forearms, feet and ankles.
2. In the case of internal contamination the committed effective dose shall be assigned to the year of intake.

#### **Article 78**

1. The undertaking shall ensure that workers under the age of 18 years are not assigned and do not carry out work as a result of which they would be regarded as exposed workers.
2. Paragraph 1 does not apply if these workers are over the age of 15 years and required as part of their training to carry out practices whereby they undergo exposure higher than the dose limits set out in Article 76.
3. The undertaking shall ensure that the following individual doses are not exceeded for persons referred to at (2) as a result of practices carried out under the undertaking's responsibility:
  - a. an effective dose of 6 mSv in a calendar year, and taking this into account:
  - b. an equivalent dose of:
    - (i) 50 mSv in a calendar year for the lens of the eye;
    - (ii) 150 mSv in a calendar year for the skin, averaged over any exposed skin area of 1 cm<sup>2</sup>, or
    - (iii) 150 mSv in a calendar year for hands, forearms, feet and ankles.
4. In the case of internal contamination the committed effective dose shall be assigned to the year of intake.

#### **Article 79**

1. For the purpose of individual monitoring and supervision the undertaking shall classify exposed workers as category A or category B workers.
2. A category A worker is an exposed worker who could receive an effective dose greater than 6 mSv in a calendar year, or an equivalent dose greater than three-tenths of the dose limits set out in Article 77.

## **Article 80**

1. The undertaking shall ensure that working conditions for a pregnant worker are such that the equivalent dose for the unborn child as a result of the work is as low as is reasonably possible and that it is unlikely that, from the time of notifying the undertaking of the pregnancy until the end of the pregnancy, this dose will exceed 1 mSv.
2. The undertaking shall ensure that if a worker has informed the undertaking that she is breastfeeding, during this period she does not carry out any practices where, based on a risk analysis, there is a relevant risk of radioactive contamination of the body.

## **Article 81**

1. In exceptional circumstances, with the exception of radiological emergencies, Our Minister of Social Affairs and Employment, or in the case of mining Our Minister, may on request by the undertaking grant exemption from the dose limits set out in Article 77, provided:
  - a. this concerns a category A worker;
  - b. the exposure is voluntary;
  - c. the exposure is time-limited;
  - d. the exposure only takes place in certain areas to be laid down;
  - e. the effective or equivalent dose that could be received is no higher than five times the values stated in Article 77 (1)(a) or twice the values stated in Article 77 (1) (b);
  - f. this does not concern an exposed apprentice, student or pregnant woman;
  - g. this does not concern a woman who is breastfeeding if there is a likelihood of contamination of the body;
  - h. reasons are given in advance by the undertaking for the exposure, and the exposure and risks are discussed in advance by the undertaking with the workers concerned, the works council or staff representation, the radiation physician and the expert, and
  - (i) the workers concerned are informed in advance by the undertaking of the precautions to be taken during the practices.
2. In a situation as referred to at (1) following completion the undertaking shall report to Our Minister of Social Affairs and Employment, or in the case of mining to Our Minister, on the practices carried out, the way in which protection against ionizing radiation was provided and the effective or equivalent dose received by the worker.
3. The undertaking shall furnish the results of the dose calculated or determined at (2) to the organization referred to in Article 91 (2) and the worker concerned.

## **Article 82**

1. The undertaking shall ensure that a person for whom an exemption as referred to in Article 81 has been granted, if as a result of the exposure referred to in that Article one of the dose limits set out in Article 77 has been exceeded, is not again exposed to ionizing radiation as a result of practices carried out under the undertaking's responsibility until such time as a radiation physician has certified that there is no objection to this.
2. Unless the radiation physician so advises, the worker shall not without his permission be excluded from his usual occupation or relocated on account of the dose limits being exceeded as referred to at (1).

## **§7.2. Requirements for workplaces**

### **Article 83**

1. The undertaking shall ensure, if necessary with a view to protection against ionizing radiation, that:
  - a. an area is designated as a controlled area, if:
    - (i) the dose that could be received by a worker in that area is equal to an effective dose higher

- than 6 mSv in a calendar year, or an equivalent dose higher than three-tenths of the dose set out in Article 77 (1) (b), or
- (ii) there is a possibility of the dispersal of radioactive substances from that area such that persons could receive a dose higher than an effective or equivalent dose set out in Article 76;
- b. an area is designated as a supervised area if the effective dose that could be received by a worker in that area is higher than 1 mSv in a calendar year and lower than 6 mSv in a calendar year, or the equivalent dose is higher than that set out in Article 76 (b) and lower than that set out at (a) (i).
2. In a controlled area and in a supervised area the undertaking shall exercise appropriate supervision of working conditions with a view to protection against ionizing radiation.
  3. The undertaking shall ensure that the extent and quality of the measures for protection against ionizing radiation are geared to the risks associated with the sources and the practices concerned.
  4. If a risk analysis shows that an area no longer meets the criteria referred to at (1) (a) or (b) so as to be designated as a controlled area or supervised area respectively, the undertaking shall ensure that the area concerned is no longer designated as a controlled area or supervised area respectively and practices involving sources, insofar as they are required to take place in a controlled area or supervised area, are discontinued in that area.

#### **Article 84**

1. As regards a controlled area the undertaking shall ensure that:
  - a. the area is delineated and access to it remains restricted to persons designated by the undertaking and that the area is controlled in line with procedures laid down by the undertaking;
  - b. measures have been taken for those cases in which there is a substantial risk of the dispersal of radioactive substances; these measures shall include entry to and exit from the area by persons and property;
  - c. there is a system for monitoring the workplace, taking into account the nature of the sources present and practices concerned;
  - d. clear warning signs and symbols relating to the area and the risks of ionizing radiation are displayed at suitable places;
  - e. persons working in the area are given written working instructions geared to the risks of ionizing radiation associated with the sources present in the area and the practices to be carried out there.
2. Further rules may be laid down by regulation of Our Minister of Social Affairs and Employment concerning a controlled area as referred to at (1).

#### **Article 85**

1. As regards a supervised area the undertaking shall ensure that:
  - a. there is a system for monitoring the workplace, taking into account the nature of the sources present and practices concerned;
  - b. clear warning signs and symbols and inscriptions relating to the area and the risks of ionizing radiation are displayed at suitable places;
  - c. persons working in the area are given written working instructions geared to the risks of ionizing radiation associated with the sources and the practices concerned.
2. Further rules may be laid down by regulation of Our Minister of Social Affairs and Employment concerning a supervised area as referred to at (1).

#### **Article 86**

In order to implement Articles 84 and 85 the undertaking, if applicable, shall carry out measurements

in the supervised and controlled area of:

- a. the dose rates, stating the nature and quality of the ionizing radiation concerned, or
- b. if open sources are present, the activity concentration in the air and the surface contamination, stating the nature and the physical and chemical condition and form thereof.

### **§7.3. Determining exposure**

#### **Article 87**

1. The undertaking shall provide an exposed worker with an appropriate personal dose monitoring device obtained by the undertaking from a dosimetry service as referred to in Article 8.
2. The undertaking shall ensure that the personal dose monitoring devices are worn by the exposed worker at the correct place or places during times of possible exposure and that these dose monitoring devices are periodically read.
3. The undertaking shall ensure that the dosimetry service periodically determines the extent to which these persons have been exposed to ionizing radiation, using the data obtained from these dose monitoring devices.
4. The undertaking shall ensure that there is an appropriate dose monitoring system in cases where exposed workers could receive relevant internal contamination under conditions normal in the work setting.
5. Our Minister of Social Affairs and Employment may lay down further rules concerning the provisions of this Article.

#### **Article 88**

1. Our Minister of Social Affairs and Employment or, in the case of mining, Our Minister, or in the case of the armed forces an authority to be designated by Our Minister of Defence, may grant exemption from the provisions of Article 87 if exposure to ionizing radiation cannot be measured, or cannot be measured properly, using personal monitoring devices, or if the effective or equivalent dose is determined in some other way.
2. Conditions may be attached to an exemption as referred to at (1) requiring the effective or equivalent dose to be estimated based on individual measurements on other exposed workers, or based on the area monitoring referred to in Article 86, or in the case of aircraft crews in a manner as referred to in Article 111 (1) (b) or in some other way.
3. Applying Section 28 (1, last part of sentence) of the Services Act, Section 4.1.3.3 of the General Administrative Law Act shall not apply to an application for an exemption as referred to at (1).

#### **Article 89**

1. If in an accident a worker has been or may have been exposed to ionizing radiation in the course of a practice, the undertaking shall ensure that the effective or equivalent doses that the worker concerned has received are determined.
2. If in a radiological emergency a worker has been or may have been exposed to ionizing radiation, the undertaking responsible for the practice that caused the radiological emergency shall ensure that individual monitoring is carried out or that the effective or equivalent doses received by the worker concerned are determined in some other way.

### **§7.4. Recording of data on exposed workers**

#### **Article 90**

1. The undertaking shall ensure that the following are recorded individually for each exposed worker:



- a. name, date of birth and sex;
  - b. classification as category A or B worker;
  - c. the doses measured or determined under Articles 87-89;
  - d. the results of the area monitoring used to calculate the effective or equivalent doses;
  - e. in the case of the exposure referred to in Articles 81 and 89, the reports on the circumstances and the measures taken.
2. The undertaking shall ensure that the data referred to at (1) (c) and (d) is retained for at least thirty years after this person discontinued the practices, or until such time as the person to whom the data relates has or would have reached the age of seventy-five years, whichever is longer.

#### **Article 91**

1. There shall be a dose recording system for keeping the results of the doses measured or determined as referred to in Articles 87, 88 and 89.
2. Our Minister of Social Affairs and Employment shall designate an organization responsible for the management of the system referred to at (1) and may lay down further rules on the organization of the system.
3. The organization referred to at (2) shall retain the recorded data at least until the person to whom the data relates has or would have reached the age of seventy-five years, and for at least thirty years after this person discontinued the practices.
4. When processing personal data in the system referred to at (1), the organization referred to at (2) may use the Citizen Service Number, or in the absence thereof, the social security and tax number, with a view to identifying the person referred to at (3).
5. Further rules may be laid down by regulation of Our Minister of Social Affairs and Employment on the modus operandi, accessibility and management of the recording system.

#### **Article 92**

1. The undertaking shall ensure that the results of the individual monitoring referred to in Articles 87, 88 and 89 are sent to the organization referred to in Article 91. In this connection the undertaking shall state where the individual dosimeter was worn or in what way the internal contamination was determined.
2. The worker shall have access to the data on his exposure.

#### **Article 93**

1. The undertaking shall ensure that the results of the individual monitoring referred to in Articles 87, 88 and 89 are furnished to:
  - a. the person referred to in Article 14 (1) of the Health and Safety at Work Act responsible for the duties referred to in Article 14 (1) (b) and (c) of that Act or the health and safety service;
  - b. the worker concerned;
  - c. the expert;
  - d. in the case of a category A worker, the radiation physician.
2. The undertaking shall immediately report the results of the individual monitoring referred to in Article 89 to the persons or service referred to at (1) and to Our Minister of Social Affairs and Employment or, in the case of mining, Our Minister.

#### **Article 94**

1. It is prohibited for an undertaking registered in the Netherlands to cause a worker who does not hold a valid radiation passport and a personal monitoring device to carry out practices as a category A worker in another European Union member state.

2. A radiation passport shall be issued to an undertaking for the worker on request by Our Minister of Social Affairs and Employment or an organization designated by him for the purpose.
3. The undertaking shall ensure that a worker has the exposure data from practices as a category A worker abroad noted in his radiation passport by the foreign undertaking and that he uses his personal monitoring device during those practices abroad.
4. On return of the worker to the Netherlands the undertaking shall immediately notify the organization referred to in Article 91 of the data in the radiation passport.
5. Regarding the provisions of this Article Our Minister of Social Affairs and Employment may lay down further rules concerning inter alia the model for the radiation passport, and applications and charges for, and loss or mislaying of, a radiation passport.

#### **Article 95**

1. It is prohibited for an undertaking to cause an outside worker to carry out practices in the Netherlands or on the Dutch Continental Shelf under the undertaking's responsibility if this worker does not hold a valid radiation passport issued by a government authority of the member state of the outside worker's undertaking on whose instructions the outside worker carries out practices.
2. The undertaking shall record the results of the individual monitoring referred to in Articles 81, 87, 88 and 89 in the radiation passport immediately after discontinuation of the practices.

#### **§7.5. Medical supervision**

#### **Article 96**

1. The undertaking shall ensure that a radiation physician carries out medical supervision of category A workers.
2. The undertaking shall ensure that all such data at the undertaking's disposal are furnished to the radiation physician as needed by the latter to gain an understanding of the state of health of the persons under his supervision and to form an opinion of conditions at the workplace insofar as these could affect their state of health.
3. The medical supervision referred to at (1) shall include:
  - a. a medical examination that takes place before designation as a category A worker and has the aim of ascertaining whether the worker is fit for his post;
  - b. periodic reviews at least once a year to check whether the category A worker is still fit for his post;
  - c. examinations of persons no longer working as category A workers if and for such time as the radiation physician considers this necessary.
4. If the radiation physician considers it necessary, a medical examination shall be followed by measures by the undertaking in connection with the protection of the worker's health.

#### **Article 97**

1. The undertaking shall ensure that as regards the fitness of category A workers to be designated as category A workers based on medical examination a radiation physician applies the following classification:
  - a. fit;
  - b. fit under certain circumstances, or
  - c. unfit.
2. The radiation physician shall immediately inform the person who underwent the examination of the fitness classification referred to at (1) in writing.

3. The person who underwent the examination may within six weeks of receiving the information referred to at (2) request a fresh examination from Our Minister of Social Affairs and Employment or, in the case of mining, Our Minister of Economic Affairs. The Minister concerned shall inform the person examined, the radiation physician and the undertaking in writing of the results of the fresh examination.

#### **Article 98**

A worker shall not be employed in a specific position as a category A worker if he is unfit for this position according to the results of the medical examination referred to in Article 97 (1).

#### **Article 99**

A medical examination by a radiation physician shall also take place if it is warranted by exposure in which dose limits were exceeded or exposure as a result of an accident or radiological emergency.

#### **Article 100**

1. The undertaking shall ensure that a medical record is kept in which at least the following are recorded for each category A worker:
  - a. the nature of the work;
  - b. the results of the examinations referred to in Articles 96, 97 and 99;
  - c. the results of the individual monitoring referred to in Articles 81, 87, 88 and 89;
  - d. if applicable, the data on a radiological emergency.
2. The undertaking shall ensure that the medical record referred to at (1) is retained at least until the person to whom the data relates has or would have reached the age of seventy-five years, and for at least thirty years after this person discontinued the practices.

### **Part 8: Exposure to natural sources**

#### **§8.1. Scope**

##### **Article 101**

As regards work activities, the provisions of this Decree relating to practices involving radioactive substances, with the exception of Articles 27-29 and Part 6, shall apply mutatis mutandis insofar as not otherwise laid down in this Part.

#### **§8.2. Notifications and licences**

##### **Article 102**

1. Our Minister shall publish in the Government Gazette a list of work activities where it is possible that the values laid down pursuant to Article 3 (1, opening) and (c) are exceeded when carrying out those work activities.
2. Before an undertaking carries out a work activity listed on the list referred to at (1), the undertaking shall ascertain whether this work activity is subject to notification under Article 103 or a licence is required under Articles 107 and 108.

##### **Article 103**

1. The undertaking shall notify Our Minister of a work activity other than a discharge before starting to carry it out.
2. This obligation does not apply if at a location:
  - a. it is a work activity where:

- (i) the activity of the radionuclides in the natural sources concerned is always lower than the value laid down pursuant to Article 3 (1, opening) and (c), or
  - (ii) the activity concentration of the natural sources concerned is lower than the value laid down pursuant to Article 3 (1, opening) and (c);
- b. it is a work activity for which a licence is required under Article 107.

3. Article 25 (3), (4), (6), (7) and (8) shall apply mutatis mutandis.
4. It may be laid down by regulation of Our Minister that in cases designated therein with a view to radiation protection paragraph 2 does not apply.
5. The obligation laid down at (1) does not apply to work activities if the application for a licence as referred to in this Decree contains data as referred to in or pursuant to Article 40 (2) concerning these sources.
6. It may be laid down by regulation of Our Minister what cases shall be exempt from the obligation laid down at (1) concerning work activities designated therein if a work activity of this kind has already been notified by another undertaking and rules laid down in the regulation have been complied with.

#### **Article 104**

If a work activity is discontinued, the undertaking shall notify Our Minister thereof as soon as possible after the discontinuation of the work activity.

Article 105 [Repealed with effect from 01/01/2014]

Article 106 [Repealed with effect from 01/01/2014]

#### **Article 107**

1. Without a licence from Our Minister it is prohibited to carry out a work activity other than a discharge.
2. The prohibition laid down at (1) does not apply at a location if:
  - a. the activity of the radionuclides in the natural sources involved in that work activity is lower than the value laid down pursuant to Article 3 (1, opening) and (c), or
  - b. the activity concentration of the natural sources involved in that work activity is lower than ten times the value laid down pursuant to Article 3 (1, opening) and (c).
3. Article 25 (3), (4), (6), (7) and (8) shall apply mutatis mutandis.
4. It may be laid down by regulation of Our Minister that in cases designated therein with a view to radiation protection paragraph 2 does not apply.
5. Applying Section 28 (1, last part of sentence) of the Services Act, Section 4.1.3.3 of the General Administrative Law Act shall not apply to an application for a licence as referred to at (1).

#### **Article 108**

1. Without a licence from Our Minister it is prohibited to discharge natural sources or carry out a work activity as a result of which natural sources are discharged.
2. The prohibition laid down at (1) does not apply if the activity of the radionuclides designated in the regulation referred to in Article 3 (1) to be discharged in a calendar year on leaving the location is lower than the value laid down in that regulation.
3. Article 25 (3), (4), (6), (7) and (8) shall apply mutatis mutandis.

4. It may be laid down by regulation of Our Minister that in cases designated therein with a view to radiation protection paragraph 2 does not apply.
5. Applying Section 28 (1, last part of sentence) of the Services Act, Section 4.1.3.3 of the General Administrative Law Act shall not apply to an application for a licence as referred to at (1).

#### **Article 109**

Rules may be laid down by regulation of Our Minister on applications for a licence for a work activity as referred to in Articles 107 and 108.

#### **Article 110**

1. If necessary in the opinion of Our Minister with a view to justification and optimization, rules may be laid down by regulation of Our Minister concerning the implementation of work activities designated therein notified under Article 103.
2. Rules may be laid down by regulation of Our Minister concerning product or material re-use and storage of waste from natural sources for categories of accidents where the activity concentration combined with the total activity of the natural sources concerned is higher than the value laid down pursuant to Article 3.
3. Article 25 (3), (4), (7) and (8) shall apply mutatis mutandis.

#### **Article 110a**

1. It is prohibited to mix radioactive wastes from natural sources in such a way that the activity concentration of those wastes is brought:
  - a. below ten times the values designated pursuant to Article 3 (1, opening) and (c), or
  - b. below the values designated pursuant to Article 3 (1, opening) and (c).
2. Without prejudice to the provisions of Articles 103 and 107, the prohibition referred to at (1) does not apply if it is demonstrated that such mixing does not cause any greater danger, greater damage or more nuisance than if the radioactive wastes from natural sources were not to be mixed.

### **§8.3. Aircraft crews**

#### **Article 111**

1. Notwithstanding Articles 102-110, the undertaking shall ensure that as regards an exposed worker forming part of an aircraft crew:
  - a. before his appointment or employment as such he is informed of the risks of cosmic radiation;
  - b. the magnitude of the effective dose received by him as a result of cosmic radiation is determined using a method laid down by Our Minister of Social Affairs and Employment;
  - c. if an effective dose of 6 mSv in a calendar year could be exceeded, in order to comply with the obligation laid down in Article 5 a modified work roster is laid down and implemented and the worker in question is classified as a category A worker;
  - d. the effective dose received by him as a result of cosmic radiation, together with the effective doses as a result of practices and work activities carried out under the undertaking's responsibility, does not exceed 20 mSv in a calendar year.
2. Articles 15 (1) and (5), 16, 17, 79, 80, 90, 91, 92 (2) and 96-100 shall apply mutatis mutandis. Article 92 (1) shall apply mutatis mutandis, subject to the proviso that instead of 'the results of the individual monitoring referred to in Articles 87, 88 and 89' it shall read 'the results of the individual monitoring referred to in Article 111 (1)'.
3. This Article does not apply to flights taking place entirely at a height of less than eight kilometres.

4. Our Minister of Social Affairs and Employment may lay down further rules concerning the provisions of this Article.

## **Part 9: Intervention**

### **Article 112**

1. An intervention shall only be carried out if the expected limitation of the damage and the harmful social effects caused by ionizing radiation is sufficient to justify the damage, the harmful social effects and the cost of the intervention.
2. The nature, extent and duration of the intervention shall be such that the benefit of the limitation of health detriment to be achieved thereby, taking into account the damage associated with the intervention, is as great as is reasonably possible.

### **Article 113**

1. Our Minister, and
  - a. in the case of the armed forces, Our Minister of Defence;
  - b. in the case of medical applications of radiation, Our Minister of Health, Welfare and Sport;
  - c. in the case of worker protection, Our Minister of Social Affairs and Employment;
  - d. in the case of discharges into surface water, Our Minister of Infrastructure and the Environment;

shall ensure that teams for technical and medical intervention and to remove radioactive contamination are available and adequately equipped to carry this out.

2. The members of these teams shall be adequately trained to carry out their duties.

### **Article 114**

Articles 87, 89, 90, 92, 93 and 96 shall apply *mutatis mutandis* to the teams referred to in Article 113 (1), subject to the proviso that the obligations referred to there rest with the person under whose responsibility the intervention is carried out.

### **Article 115**

The undertaking shall ensure that steps are taken to prepare for an intervention in the event of a radiological emergency occurring at the location. The undertaking shall draw up an intervention plan for each location and test it regularly.

### **Article 116**

1. If a radiological emergency occurs at the location, the undertaking shall immediately take all appropriate measures to limit its consequences.
2. The undertaking shall immediately notify the mayor of the municipality where the situation has occurred of the radiological emergency.
3. The undertaking shall immediately carry out a provisional assessment of the circumstances and the consequences of the situation and notify the mayor and Our Minister thereof.
4. The undertaking shall ensure that every assistance is given to an intervention carried out by an administrative authority.

### **Article 117**

1. Our Ministers referred to in Article 113, each insofar as the interests referred to in that Article are concerned, shall lay down rules on the carrying-out of interventions.

2. The person under whose responsibility the intervention is carried out shall ensure that the consequences and effectiveness of an intervention are determined and recorded.

#### **Article 118**

1. Articles 48, 49, 76 and 77 do not apply in the case of intervention in a radiological emergency.
2. In the case of intervention in a radiological emergency the following shall apply as dose constraints on the effective dose for workers and emergency workers:

life-saving work: 750 mSv

saving important material interests: 250 mSv

supporting or carrying out measurements, evacuation,

iodine prophylaxis, public order and safety: 100 mSv

3. The values laid down at (2) for life-saving work shall only be exceeded if that is necessary to save human life or secure important material interests, the worker or emergency worker concerned has been informed by the undertaking of the risks of the intervention, and the intervention is carried out voluntarily.
4. Article 113 (2) and Article 114 shall apply mutatis mutandis to workers and emergency workers entrusted with the duties referred to at (2) in an intervention.

#### **Article 119**

1. Our Ministers referred to in Article 113, each insofar as the interests referred to in that Article are concerned, or the undertaking may designate a situation as a situation resulting in long-term exposure as a result of a radiological emergency or an earlier practice or work activity.
2. If the situation referred to at (1) falls under the responsibility of an undertaking, Our Ministers referred to in Article 113 may require the undertaking to carry out the intervention.
3. In a case as referred to at (1), the person under whose responsibility the intervention is carried out shall be responsible, insofar as is necessary with a view to the danger of exposure, for:
  - a. delineating the area in question;
  - b. introducing an exposure monitoring system;
  - c. carrying out the intervention in accordance with an action plan approved by Our Minister concerned;
  - d. controlling access to or use of the locations or buildings in the delineated area.
4. As regards intervention in a case as referred to at (1), this Decree, with the exception of paragraphs 4.2-4.4 and Articles 39 (b), 48 and 114-118, shall apply mutatis mutandis.

### **Part 10: Records, Further Requirements and Exemptions**

#### **Article 120**

1. An undertaking carrying out practices shall maintain records of those practices. These records shall be kept in a management system.
2. The records shall include at least:
  - a. the name of the legal person and the responsible general coordinating expert, coordinating expert or supervisory expert;
  - b. the place where the practices are carried out;

- c. a description of the nature and extent of the practices;
  - d. the risk analysis.
3. Further rules on the content and rules on the retention periods for the records shall be laid down by regulation of Our Minister.

#### **Article 120a**

1. An undertaking carrying out practices involving a high-activity source shall furnish Our Minister with the relevant data concerning that source in writing.
2. Further rules shall be laid down by regulation of Our Minister concerning that data and when it shall be furnished.

#### **Article 121**

1. A person who carries out industrial radiography practices at changing places shall keep records of those practices for each location.
2. The records referred to at (1) shall be kept in a management system.
3. The person maintaining records as referred to at (1) shall retain the data comprising those records for at least three years after the calendar year to which they relate.
4. Further requirements for the records referred to at (1) shall be laid down by regulation of Our Minister.
5. The obligation laid down at (1) does not apply if the number of images taken per calendar year is anticipated to be less than 100.

#### **Article 122**

1. A person carrying out practices shall meet further requirements in respect of the rules laid down in or pursuant to this Decree.
2. Further requirements relating solely to the protection of workers against ionizing radiation as a result of practices shall be laid down:
  - a. in the case of mining: by Our Minister;
  - b. in the case of other practices: by an official designated by Our Minister of Social Affairs and Employment.
3. If these further requirements do not relate to the protection of workers against ionizing radiation in practices to be carried out by them, they shall be laid down by the inspector, or Our Minister of Health, Welfare and Sport, insofar as the interests coming under them are concerned, or if mining on the continental shelf is concerned, Our Minister.
4. Further requirements concerning the interests referred to at both (2) and (3) shall be laid down by the administrative authorities referred to in those paragraphs jointly.

#### **Article 123**

1. In special cases Our Ministers, or Our Minister of Defence in the case of the armed forces, may grant exemption from the requirements in Parts 3, 5, 6, 7, 8 and 10 of this Decree.
2. Conditions may be attached to the exemption.
3. Applying Section 28 (1, last part of sentence) of the Services Act, Section 4.1.3.3 of the General Administrative Law Act shall not apply to an application for an exemption as referred to at (1).



## **Part 11: Transitional and Final Provisions**

### **Article 124**

If urgently necessary in the interests of protecting against ionizing radiation in the opinion of Our Ministers, and it is not possible in their opinion to wait for an amendment to this Decree, rules may be laid down by regulation of Our Ministers that derogate from this Decree but have the effect intended by this Decree. Any such regulation shall cease to have effect one year after entering into force or, if within that time limit an amendment to the provision concerned of this Decree has entered into force, when that amendment enters into force. Our Ministers may extend the time limit once by a maximum of one year by Ministerial Regulation.

### **Article 125**

The Radiation Protection (Nuclear Energy Act) Decree and the Radioactive Materials (Registration) and Nuclear Energy Act Inspection Services (Charges) Decree shall be repealed.

### **Article 126**

[Amends the Continental Shelf Mining Regulation.]

### **Article 127**

1. A licence granted before the date of entry into force of this Decree pursuant to:
  - a. Section 29 of the Act in conjunction with Articles 6 and 7 of the Radiation Protection (Nuclear Energy Act) Decree as that decree read until the date of entry into force of this Decree;
  - b. Section 34 of the Act in conjunction with Article 8 of the Radiation Protection (Nuclear Energy Act) Decree as that decree read until the date of entry into force of this Decree;
  - c. Section 26 of the Continental Shelf Mining Act in conjunction with Article 167 of the Continental Shelf Mining Regulation as that read until the date of entry into force of this Decree shall be based after the date of entry into force of this Decree on Article 23, 24, 25 or 108 of this Decree.
2. A practice involving apparatus for which before the date of entry into force of this Decree a licence has been granted under or pursuant to Section 34 of the Act, in conjunction with Article 8 (1) (b) of the Radiation Protection (Nuclear Energy Act) Decree as that decree read until the date of entry into force of this Decree, shall be deemed to have been notified in accordance with Article 21 of this Decree.
3. An undertaking carrying out a practice or work activity involving a radioactive substance for which no licence is required pursuant to Section 29 of the Act in conjunction with Article 6 (1) and (2) and Article 7 (1) and (2) of the Radiation Protection (Nuclear Energy Act) Decree as that decree read until the date of entry into force of this Decree, or pursuant to Section 34 of the Act, but for which the undertaking does require a licence under or pursuant to this Decree shall submit an application in accordance with Article 43 of this Decree within 12 months of the entry into force of this Decree. Until such time as Our Ministers have decided upon that application the practice shall be deemed to have been carried out in accordance with this Decree.
4. An undertaking carrying out a work activity for which no notification or licence is required pursuant to the Act until the date of entry into force of this Decree but for which notification is required pursuant to Part 8 of this Decree shall give notification of the activity before a date to be laid down by Our Ministers. Until that date the work activity shall be deemed to have been notified in accordance with this Decree.
5. An undertaking carrying out a work activity for which a licence has been granted pursuant to the Act until the date of entry into force of this Decree but for which notification is required pursuant to Part 8 of this Decree shall be deemed to have given notification of the activity in accordance with Article 103 of this Decree. The conditions attached to the licence shall remain in force after the date of entry into force of Part 8 of this Decree.

6. Apparatus as referred to in Section 34 of the Act in conjunction with Article 4 (2) of the Radiation Protection (Nuclear Energy Act) Decree as that decree read until the date of entry into force of this Decree, or a practice involving a radioactive substance as referred to in Section 29 of the Act in conjunction with Article 6 (3) of the Radiation Protection (Nuclear Energy Act) Decree as that decree read until the date of entry into force of this Decree shall be deemed to be apparatus approved under Article 21 (2) (d) of this Decree or a practice of a type approved under Article 26 (1) (a) of this Decree respectively.
7. Practices to which (1) and (2) apply and that are not justified under Article 4, or that are in a category that is not justified, shall be deemed to be justified on the date of entry into force of this Decree.
8. Practices notified in accordance with the Radiation Protection (Nuclear Energy Act) Decree before the entry into force of this Decree that are not justified under Article 4, or that are in a category that is not justified under Article 4, shall be equated with practices that are justified under Article 4.

#### **Article 128**

Applications for a licence pursuant to Section 29 of the Act in conjunction with Articles 6 and 7 of the Radiation Protection (Nuclear Energy Act) Decree as that decree read until the date of entry into force of this Decree, and notifications of apparatus pursuant to Article 72 of the Radiation Protection (Nuclear Energy Act) Decree made before the date of entry into force of this Decree, shall be decided under the rules pursuant to the Radiation Protection (Nuclear Energy Act) Decree as that decree read until the date of entry into force of this Decree.

#### **Article 129**

The handling of objections or appeals lodged before the date of entry into force of this Decree against licences as referred to in Article 127 that have been granted or refused in accordance with the articles of the Radiation Protection (Nuclear Energy Act) Decree as that decree read until the date of entry into force of this decree shall remain subject to those articles of this Radiation Protection (Nuclear Energy Act) Decree and the rules laid down pursuant to those articles, subject to the proviso that in the event of an objection or appeal resulting in the quashing of the decision to grant a licence after the date of entry into force of this Decree, a fresh decision shall be taken applying this Decree.

#### **Article 130**

1. Article 122 of this Decree shall apply to a person upon whom there was an obligation before the date of entry into force of this Decree to comply with a further requirement as referred to in Article 75 in conjunction with Article 82b of the Radiation Protection (Nuclear Energy Act) Decree as that decree read until the date of entry into force of this Decree; after the date of entry into force of this Decree that further requirement shall be based on Article 122.
2. Article 123 of this Decree shall apply to an exemption granted before the date of entry into force of this Decree pursuant to Article 77 in conjunction with Article 82d of the Radiation Protection (Nuclear Energy Act) Decree as that decree read until the date of entry into force of this Decree; after the date of entry into force of this Decree that exemption shall be based on Article 123.

#### **Article 131**

After the entry into force of this Decree:

- a. the decision of 31 August 1987 concerning recognition of the Centrale Organisatie Voor Radioactief Afval N.V. as a collection service shall be based on Article 37 (7) of this Decree;
- b. the decree instituting a centralized system for the storage of radiological data and establishment of a radiation passport shall be based on Articles 91 and 94 of this Decree;
- c. the decisions pursuant to Article 25 (1) in conjunction with Article 81 (1) of the Radiation Protection (Nuclear Energy Act) Decree as that decree read until 1 March 2002 shall be based on Article (1) of this Decree;
- d. the Designation of Electron Microscopes (Nuclear Energy Act) Regulation 1998 shall be based

- on Article 21 (2) (d) of this Decree;
- e. the Designation of Smoke Detectors (Nuclear Energy Act) Regulation 2000-II shall be based on Article 26 (2) of this Decree.

#### **Article 132**

1. Until a date to be laid down by regulation of Our Ministers, a person holding a diploma for training at the levels referred to in the Radioactive Substances and Apparatus Experts (Recognition of Training) Regulation as that regulation read until the date of entry into force of this Decree and the Guideline of 20 November 1984 on the recognition of training for radioactive substances and apparatus experts shall be deemed to be an expert registered in a register as referred to in Article 7 (2).
2. Until a date to be laid down by regulation of Our Ministers, training recognized in accordance with the Radioactive Substances and Apparatus Experts (Recognition of Training) Regulation as that regulation read until the date of entry into force of this Decree and the Guideline of 20 November 1984 on the recognition of training for radioactive substances and apparatus experts shall be deemed to be training as referred to at (2).
3. Until a date to be laid down by Ministerial Regulation, Our Ministers and Our Minister of Health, Welfare and Sport may recognize training as referred to at (2).

#### **Article 133**

[Amends the Nuclear Facilities, Fissionable Materials and Ores Decree.]

#### **Article 134**

[Amends the Fissionable Materials, Ores and Radioactive Materials (Transport) Decree.]

#### **Article 135**

[Amends the Nuclear Energy Act Charges Decree 1981.]

#### **Article 136**

This Decree shall enter into force on a date to be laid down by Royal Decree, which may be different for the various articles or parts thereof.

#### **Article 137**

This Decree shall be cited as the 'Radiation Protection Decree'.

We order and command that this Decree with its Explanatory Memorandum be published in the Bulletin of Acts and Decrees.

Tavarnelle, 16 July 2001

Beatrix

The State Secretary for Social Affairs and Employment,  
J. F. Hoogervorst  
The Minister of Housing, Spatial Planning and the Environment,  
J.P. Pronk  
The Minister of Health, Welfare and Sport,  
E. Borst-Eilers

Issued this sixth day of September 2001.

The Minister of Justice,  
A. H. Korthals

## Annex: Definitions of Parameters and Units

### 2.1. Introduction

Various types of parameters can be identified for radiation protection purposes:

1. Physical parameters describing a radiation field or interaction between radiation and matter (these parameters are laid down in Part 2.2).
2. Limiting parameters are defined to prevent or limit the harmful effects of exposure to radiation. These parameters (see Part 2.3) are used in the legislation and regulations to set standards, but they are not directly measurable.
3. Operational parameters (see Part 2.4) are defined for exposure to external radiation sources and are used to estimate limiting parameters. Operational parameters are measurable.
4. Operational parameters for radioactive substances (see Part 2.5) that are defined by the Dutch government for exposure to radioactive substances and are used to lay down the maximum amounts of radioactive substances that are permitted to be used for practices or work activities.

### 2.2. Physical parameters

The most fundamental radiometric parameters are the number of particles emitted by a radiation source or the source strength and the number of particles emitted per unit of time.

The *fluence*,  $\Phi$ , is the quotient of  $dN$  and  $da$ , where  $dN$  is the number of particles penetrating a sphere of diameter  $da$ :

$$\Phi = \frac{dN}{da}$$

(2.1)

The unit for fluence is  $m^{-2}$ .

Activity is not a radiometric parameter; it is defined as follows<sup>1</sup>:

The *activity*,  $A$ , of an amount of a radionuclide in a certain energy state at a given time is the quotient of  $dN$  and  $dt$ , where  $dN$  represents the expectation value of the number of spontaneous nuclear transitions from that energy state during time  $dt$ :

$$A = \frac{dN}{dt}$$

(2.2)

The unit for activity is  $s^{-1}$ , with the special name becquerel (Bq).

The *activity concentration* (activity per unit mass) is the quotient of  $A$  and  $m$ , where  $A$  is the activity of a mass element with mass  $m$ .

The surface contamination is the quotient of  $A$  and  $O$ , where  $A$  is the activity on or in a surface  $O$ .

Dosimetric parameters, such as kerma and absorbed dose, are essentially the product of radiometric parameters and interaction coefficients.

The parameter kerma is only defined for indirect ionizing radiation such as photons and neutrons.

The *kerma*,  $K$ , is the quotient of  $dE_{tr}$  and  $dm$ , where  $dE_{tr}$  is the sum of the kinetic energy transferred to all secondary charged particles released by uncharged radiation particles in a material with mass  $dm$ :

$$K = \frac{dE_{tr}}{dm}$$

(2.3)

The unit for kerma is  $J\ kg^{-1}$ , with the special name gray (Gy).

The *absorbed dose*,  $D$ , is the quotient of  $d$  and  $dm$ , where  $d$  is the average energy released by ionizing radiation on material in a volume element with mass  $dm$ :

$$D = \frac{d\bar{E}}{dm}$$

(2.4)

The unit for absorbed dose is  $J\ kg^{-1}$ , with the special name gray (Gy).

The parameter 'lineic energy transfer' is introduced for charged particles. In the case of *unrestricted*

1) See also the definition by the ICRU (1998b) in a separate category.

lineic energy loss<sup>2</sup>,  $L_\infty$ , there is no restriction on the limit value of the energy loss, and  $L_\infty$  is also referred to as  $L$ , where  $dE$  is the average energy that a particle with energy  $E$  loses when covering a distance  $d$  in a material as a result of collisions with electrons:

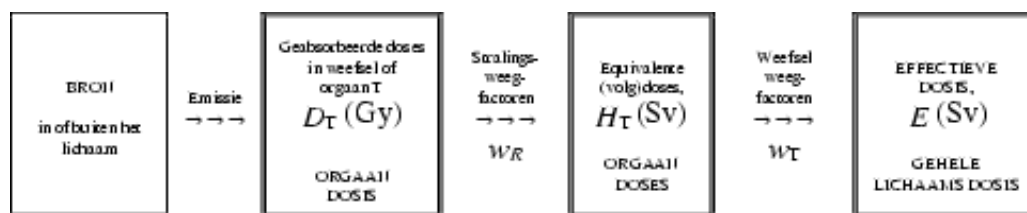
$$L_\infty = \frac{dE}{dI} \quad (2.5)$$

The unit for  $L_\infty$  is  $J m^{-2}$ , but  $L_\infty$  is usually expressed as  $keV \mu m^{-1}$ .

### 2.3. Limiting parameters

Average effective doses in organs or tissue<sup>3</sup> can be calculated based on the description of a radiation field.

**Fig. 2.1. Chart for the calculation of the Absorbed Doses,  $D_T$ , the Committed Equivalent Doses,  $H_T$ , and the Effective Dose,  $E$ , received by a person from a radiation source**



For radiation protection purposes the *organ dose*,  $D_T$ , is defined as the quotient of the total energy  $T$  released in a tissue or organ and the mass  $m_T$  of that organ or tissue:

$$D_T = \frac{E_T}{m_T} \quad (2.6)$$

The special unit for organ dose is gray (Gy).

The *equivalent dose*  $H_T$ , in a tissue or organ  $T$  is the sum of the products of the average absorbed dose  $D_{T,R}$  in a tissue or organ due to radiation  $R$  and the radiation weighting factor  $w_R$ :

$$H_T = \sum_R w_R D_{T,R} \quad (2.7)$$

The unit for equivalent dose is  $J kg^{-1}$ , with the special name sievert (Sv).

The *committed equivalent dose*,  $H_T(\tau)$ , is the integral over time  $\tau$  of the equivalent dose rate in tissue or organ  $T$  that an individual will receive as a result of intake of activity at time  $t$ :

$$H_T(\tau) = \int_{t_0}^{t_0 + \tau} H_T(t) dt \quad (2.8)$$

where  $H_T(\tau)$  represents the respective equivalent dose rate in organ or tissue  $T$  at time  $t$ , and  $\tau$  the period in years over which the integration is made. When  $\tau$  is not given, a period of 50 years is assumed for adults and up to the age of 70 for children. The unit for equivalent dose is  $J kg^{-1}$ , with the special name sievert (Sv).

The *radiation weighting factor* ( $w_R$ ) is a dimensionless factor used to weight the absorbed dose  $D_{T,R}$  in a tissue or organ  $T$  so as to take into account the biological effectiveness of radiation type  $R$  when determining the equivalent dose  $H_T$  in that organ or tissue.

The value of the radiation weighting factor  $w_R$  depends on the type and energy of the external radiation field, or the type and energy of the radiation emitted by a radionuclide in the organism. If the radiation field is made up of types and energies with different  $w_R$  values, the absorbed dose should be subdivided into blocks each with its own  $w_R$  value, which should then be aggregated to

2) International Commission on Radiological Protection, 1990 Recommendations of the ICRP. Publication 60, Annals of the ICRP 21. No. 1-3 (Pergamon Press, Oxford).

3) International Commission on Radiological Protection, Conversion Coefficients for use in radiological protection against external radiation. Publication 74, Annals of the ICRP 26 No. 3-4 (Pergamon Press, Oxford).

obtain the total equivalent dose. Alternatively, the absorbed dose can be expressed as a continuous energy distribution where each element of the absorbed dose from the energy element between  $E$  and  $E + dE$  is multiplied by the respective  $w_R$ . The radiation weighting factors for different radiation types are provided in Table 2.1.

In the case of radiation types and energies that are not shown in Table 2.1,  $w_R$  can be approximated by calculating the average quality factor  $Q$  at a depth  $d$  of 10 mm in the ICRU sphere (see Part 2.4).

Table 2.1: Radiation weighting factors  $w_R$

Type of radiation and energy field	$w_R$
Photons, all energies	1
Electrons and muons, all energies <sup>1</sup>	1
Neutrons, energy <10 keV	5
10 – 100 keV	10
> 100 keV – 2 MeV	20
> 2 – 20 MeV	10
> 20 MeV	5
Protons, with the exception of recoil protons, Energy > 2 MeV	5
Alpha particles, fission fragments, heavy nuclei	20

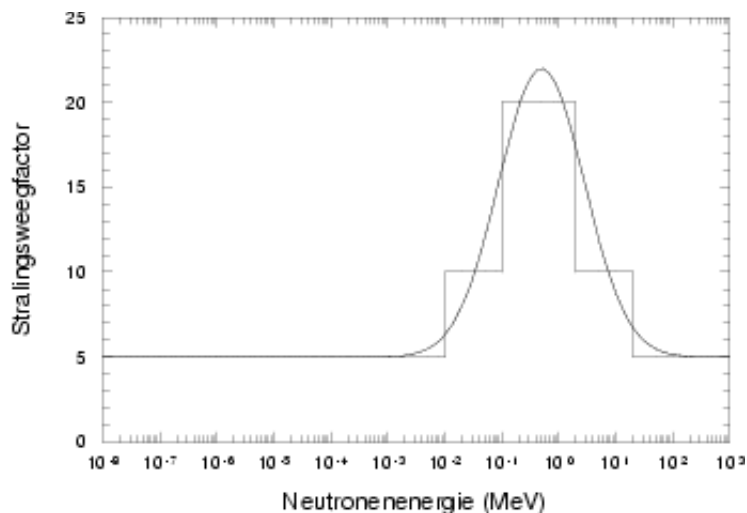
1 With the exception of Auger electrons emitted by nuclei bound to DNA

Problems can occur in calculations for neutrons with energy  $E_n$  (in MeV) when using incremental values. In such cases it is sometimes better to use the continuous function (see Fig. 2.2) described by the following mathematical equation:

$$w_R = 5 + 17e^{-\frac{\ln(2E_n)^2}{6}} \quad (2.9)$$

Fig. 2.2: Radiation weighting factors ( $w_R$ ) for neutrons

The flowing line should be regarded as an approximation.



The sensitivity to radiation of the various tissues and organs in the body differs with respect to the induction of stochastic effects.

The *tissue weighting factor* ( $w_T$ ) is a factor used to calculate the contribution made by the equivalent dose in a tissue or organ ( $H_T$ ) to the effective dose ( $E$ ). This factor is related to the sensitivity to radiation of the organs and tissues with respect to stochastic effects. The values are provided in Table 2.2.

Table 2.2: Tissue weighting factors  $w_T$  for the weighting of the equivalent dose  $H_T$

Tissue or organ T	Tissue weighting factor $w_T$ *
Gonads	0.20
Red bone marrow	0.12
Large intestine (colon)	0.12****
Lungs	0.12
Stomach	0.12
Bladder	0.05
Breast tissue	0.05
Liver	0.05
Oesophagus	0.05
Thyroid gland	0.05
Skin	0.01
Bone surface	0.01
Remainder tissues and organs	0.05** ** **

\* The values are based on a reference population with equal numbers of men and women of varying ages. When determining the effective dose they apply to workers and the population as a whole, and to both sexes.

\*\* For the purposes of calculation the following are counted as remainder tissues and organs: adrenal glands, brain, upper large intestine (ascending colon), small intestine, kidneys, muscles, pancreas, spleen, thymus, extrathoracic region of respiratory tract (ET: see ICRP Publication No. 68)<sup>4</sup> and uterus. The list includes organs that can be irradiated selectively. Some of the organs on the list are known to be susceptible to cancer. If it subsequently emerges that there are other tissues and organs that are susceptible to neoplasms they will be added with their own  $w_T$  values or to this list of remainder organs. This latter may also include other selectively irradiated tissues and organs.

\*\*\* In exceptional cases where only one of the remainder tissues or organs receives an equivalent dose exceeding the highest equivalent dose in one of the twelve organs that have their own weighting factors, a weighting factor of 0.025 should be used for that tissue or organs, and a weighting factor of 0.025 applied to the average equivalent dose in the other remainder tissues and organs as defined above.

\*\*\*\* The colon is the upper part of the large intestine (ULI = ascending colon + transverse colon) plus the lower part of the large intestine and other parts (LLI = descending colon + lower parts). The ICRP gives recommendations on the use of tissue weighting factors for various parts of the colon in Publication No. 67<sup>4</sup>.

The *effective dose*,  $E$ , is the sum of the weighted equivalent doses in all the tissues and organs listed in Table 2.2 from internal and external irradiation:

$$E = \sum_T w_T H_T \quad (2.10)$$

where  $H_T$  is the equivalent dose in tissue or organ T and  $w_T$  is the tissue weighting factor as provided in Table 2.2. The unit for effective dose is  $J\ kg^{-1}$ , with the special name sievert (Sv).

The effective dose is a double-weighted organ dose that can also be described as:

$$E = \sum_T w_T \sum_R w_R D_{T,R} \quad (2.11)$$

where  $D_{T,R}$  is the average absorbed dose in tissue or organ T due to radiation type R.

4) International Commission on Radiological Protection, Publication 68 (Annals of the ICRP Vol. 24 No. 4) Dose coefficients for Intakes of Radionuclides by Workers (Pergamon Press, Oxford).

4) International Commission on Radiological Protection, Publication 67, (Annals of the ICRP Vol. 23 No. 3/4) Age-dependent Doses to Members of the Public from Intake of Radionuclides: Part 2 (Pergamon Press, Oxford).

The *committed effective dose*  $E(\tau)$  is the sum of the committed equivalent organ or tissue doses expected due to intake of radionuclides by the body from the external environment, each multiplied by the respective tissue weighting factor  $w_T$ .

$$E(\tau) = \sum_T w_T H_T(\tau)$$

(2.12)

In  $E(\tau)$  and  $H_T(\tau)$ ,  $\tau$  represents the number of years over which the committed dose is integrated. The unit for effective dose is  $\text{J kg}^{-1}$ , with the special name sievert (Sv). Unless otherwise stated,  $\tau$  is 50 years for adults and 70 years for children.

## 2.4. Operational parameters for external radiation sources

The *dose equivalent*,  $H$ , is the product of the quality factor,  $Q$ , and the absorbed dose at a point,  $D$ , expressed in ICRU tissue:

$$H = DQ$$

(2.13)

The unit for dose equivalent is the sievert (Sv).

The dose equivalent is calculated using a quality factor  $Q$ , not the radiation weighting factor  $w_R$ , which is used to calculate the equivalent dose.

The *quality factor* ( $Q$ ) is a factor that weights the absorbed dose at a point in a tissue or organ for the biological effectiveness of the charged particles producing the absorbed dose. The quality factor is defined as a function of the unrestricted lineic energy loss ( $L_\infty$ ) in water at the reference point (see Table 2.3).

**Table 2.3. Relation between quality factor  $Q(L_\infty)$  and unrestricted lineic energy loss  $L_\infty$**

Unrestricted lineic energy loss $L_\infty$ in water ( $\text{keV } \mu\text{m}^{-1}$ )	$Q(L_\infty)$
$L_\infty > 10$	1
$10 < L_\infty < 100$	$0.32 L_\infty - 2.2$
$L_\infty > 100$	$300 / \sqrt{L_\infty}$

The *average quality factor*,  $\bar{Q}$ , is the average value of the quality factor  $Q$  at a point in a tissue when the absorbed dose is released by particles with different  $L$  values. This factor is calculated using the equation:

$$\bar{Q} = \frac{1}{D} \int_0^\infty Q(L_\infty) D(L_\infty) dL_\infty$$

(2.14)

where  $Q(L_\infty)$  is the quality factor at the reference point,  $L_\infty$  the unrestricted lineic energy loss, and  $D(L_\infty)dL_\infty$  the absorbed dose in the interval between the values  $L_\infty$  and  $L_\infty + dL_\infty$ . The relation between  $L_\infty$  and  $Q(L_\infty)$  is shown in Table 2.3.

When defining operational parameters for environmental dosimetry and in order to calibrate personal dosimeters a very simple phantom known as the 'ICRU sphere' is used. This is a sphere with a diameter of 30 cm and a density of  $1 \text{ g cm}^{-3}$ . The sphere is made up of the following materials, with the mass fraction shown in brackets: O (76.2%) H(10.1%) C(11.1%) N(2.6%). This corresponds to the composition of soft tissue. The ICRU sphere is designed to be a model of the human trunk.

An *expanded field* is a field derived from an actual radiation field where the fluence (see 2.2) and the values of its directional and energy distributions are the same everywhere in the measured volume as at the reference point in the actual radiation field.

An *expanded and aligned field* is a radiation field where the fluence and its directional and energy distribution are the same as in the expanded field but the fluence is unidirectional.

*Area monitoring*



The *environmental dose equivalent*,  $H^*(d)$ , at a point in a radiation field is the dose equivalent that would be brought about in the corresponding but expanded and aligned field in the ICRU sphere at depth  $d$ . The unit for environmental dose equivalent is the sievert (Sv). In the case of penetrating radiation a value of 10 mm is recommended for  $d$ , and for poorly penetrating radiation a value of  $d$  of 0.07 mm for the skin and 3 mm for the eyes. The factors needed to convert from environmental dose equivalent to effective dose are set out in ICRP Publication No. 74<sup>5</sup>.

The *environmental dose equivalent rate*  $\dot{H}^*(d)$  is the environmental dose equivalent per unit of time. The unit for environmental dose equivalent rate is  $\text{Sv s}^{-1}$ .

The *directional dose equivalent*  $H'(d, \theta)$  is the dose equivalent at a point in the radiation field that would be brought about by the corresponding expanded field in the ICRU sphere at depth  $d$ , on a beam in a particular direction, where  $\theta$  is the angle between the direction of incidence of the radiation and a reference direction, and  $d$  is the depth in mm below the surface of the ICRU sphere. In the case of penetrating radiation a value of 10 mm is recommended for  $d$ , and for poorly penetrating radiation a value of 0.07 mm for the skin and 3 mm for the eyes. The unit for directional dose equivalent is the sievert (Sv). The factors that can be used to convert from directional dose coefficient to effective dose are set out in ICRP Publication No. 74 and ICRU Publication No. 57<sup>6</sup>.

#### *Individual monitoring using personal monitoring devices*

The *personal dose equivalent*,  $H_P(d)$ , is the dose equivalent in soft tissue at a depth  $d$  below a certain point on the body. The unit for personal dose equivalent is the sievert (Sv). In the case of penetrating radiation a value of 10 mm is recommended for  $d$ , and for poorly penetrating radiation a value for  $d$  of 0.07 mm for the skin and 3 mm for the eyes. *The factors required for calculation are set out in ICRP Publication No. 74.*

## 2.5. Operational parameters for radioactive substances

The *radiotoxicity equivalent*  $Re$  of a radionuclide is the activity causing a committed effective dose of 1 sievert in the case of full direct intake (ingestion or inhalation).

The  $Re$  for a radionuclide is the inverse effective dose coefficient for that nuclide:

$$Re = \frac{1}{e(g)}$$

(2.15)

where  $e(g)$  is the effective dose coefficient for age group  $g$ , in accordance with instructions laid down by Our Minister for determining the committed effective dose. The unit for radiotoxicity equivalent is Bq.

When calculating  $Re$  the effective dose coefficient for the age group >17 years is always used.

#### *Radiotoxicity equivalent for ingestion ( $Re_{ing}$ )*

One radiotoxicity equivalent for ingestion ( $Re_{ing}$ ) of a radionuclide is the activity that on ingestion causes a committed effective dose of 1 sievert in a reference person aged over 17 years in accordance with instructions laid down by Our Minister for determining the committed effective dose:

$$Re_{ing} = \frac{1}{e_{ing}}$$

(2.16)

where  $e_{ing}$  is the dose coefficient for the age group >17 years for radionuclide  $i$ , in accordance with instructions laid down by Our Minister for determining the committed effective dose.

The unit for radiotoxicity equivalent is the becquerel (Bq).

#### *Radiotoxicity equivalent for inhalation ( $Re_{inh}$ )*

One radiotoxicity equivalent for inhalation ( $Re_{inh}$ ) of a radionuclide is the activity that on inhalation

5) International Commission on Radiological Protection, Conversion Coefficients for use in radiological protection against external radiation. Publication 74, Annals of the ICRP 26 No. 3-4 (Pergamon Press, Oxford).

6) Conversion coefficients for use in radiological protection against ionizing radiation, ICRU report 57. International Commission on Radiation Units and Measurements (Bethesda, Maryland).

causes a committed effective dose of 1 sievert in a reference person aged over 17 years, as referred to in the last column of Tables 4.1, 4.2 and 6 and in Table 5:

$$Re_{inh} = \frac{1}{e_{inh}} \quad (2.17)$$

where  $e_{inh}$  is the inhalation dose coefficient for the age group >17 years for radionuclide  $i$ , in accordance with instructions laid down by Our Minister for determining the committed effective dose. The unit for radiotoxicity equivalent is the becquerel (Bq).

*Correction factors for discharges expressed in Re*

Factors to correct the radiotoxicity equivalent of a particular radionuclide for the physical half-life of that radionuclide, for discharges into water or a public sewer. The amounts discharged expressed in  $Re$  are corrected as follows before assessment:

$$Te \text{ toetsen aantal } Re = \sum_i Re_i CR_i \quad (2.18)$$

where:

$Re_i$  = the amount of radionuclide  $i$  discharged, expressed in  $Re$ , and  
 $CR_i$  = the correction factor for discharges of radionuclide  $i$

*Table 2.4: Correction factors for discharges into air and water*

*Correction factor (CR) for discharges, expressed in Re into air CRa and water CRw, depending on the physical half-life of the radionuclide discharged*

Half-life	$\leq 5d$	$5 < T_{1/2} \leq 7.5d$	$7.5d < T_{1/2} \leq 15d$	$15d < T_{1/2} \leq 25j$	$25 < T_{1/2} \leq 250j$	$250j < T_{1/2}$
Discharges into the air $CR_a$	1	1	1	1	10	100
Discharges into water $CR_w$	0.001	0.01	0.1	1	10	100